DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 1996

Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Premarket Approval of Spine-Tech, Inc.'s
BAK™ Interbody Fusion System - ACTION

The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved ___ Disapproved ___ Date _____

Prepared by H.S. Rhodes, CDRH, HFZ-410, 6/16/96, 594-2036
Prepared by S.Niver, CDRH, HFZ-410, 9/12/96, 594-2036
Prepared by M.Melkerson, CDRH, HFZ-410, 9/12/96, 594-2036

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DRAFT

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. _____]

Spine-Tech, Inc.; PREMARKET APPROVAL OF BAK™ Interbody Fusion System with instrumentation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Spine-Tech, Inc., Minneapolis, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the BAK™ Interbody Fusion System with instrumentation. After reviewing the recommendation of the Orthopedic and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on September 20, 1996, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

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FOR FURTHER INFORMATION CONTACT:

Mr. Mark N. Melkerson,

Center for Devices and Radiological Health (HFZ-410),

Food and Drug Administration,

9200 Corporate Blvd.,

Rockville, MD 20850,

301-594-2036.

SUPPLEMENTARY INFORMATION: On August 28, 1995, Spine-Tech, Inc., Minneapolis, MN 55439-2029, submitted to CDRH an application for premarket approval of the BAK™ Interbody Fusion System with instrumentation. This device is an intervertebral body fusion device. It is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). BAK™ devices are to be implanted via an open anterior or posterior approach. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

On May 23, 1996, the Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application.

On September 20, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity For Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: _____.

_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Richard Jansen, Pharm.D.
Vice President
Regulatory and Clinical Affairs
Spine-Tech, Inc.
7375 Bush Lake Road
Minneapolis, Minnesota 55439-2029

SEP 20 1996

Re: P950002
BAK™ Interbody Fusion System with instrumentation
Filed: August 28, 1995
Amended: February 22, 1996; April 15, 1996; April 19, 1996; April 22, 1996; May 10, 1996; July 26, 1996; August 12, 1996; August 23, 1996; September 11, 1996; and September 13, 1996.

Dear Dr. Jansen:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the BAK™ Interbody Fusion System with instrumentation. The device is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). BAK™ devices are to be implanted via an open anterior or posterior approach.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed) and the following condition that you provide updated promotional and advertising materials in your annual reports. You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the post-approval requirements in the enclosure, the post-approval reports must include the following information:

1. In order to assess the long-term performance of the BAK™ Interbody Fusion System, please conduct a post-approval study to obtain a total of 6 years of postoperative data from a minimum of 100 patients from each surgical approach group (i.e., anterior and posterior). These outcomes should be submitted to the FDA as part of your annual report. As stated in your PMA amendment received by FDA on September 11, 1996, your post-approval study will incorporate the following elements:

   a. inclusion of 150 patients implanted from the anterior approach and 150 patients implanted from the posterior approach. Patients will be selected from 3 to 6 sites which participated in the original IDE study. With an approximate 10% loss of patients to follow-up per each of the remaining four years, this should yield a minimum of 100 patients per anterior and posterior approach;

   b. collection of the following information biennially for each patient (because the designated patient population has already reached the two-year time point, patients will be evaluated at his/her 4 and 6-year time points):

      (1) a description of any surgical interventions which include reoperations, removals, revisions, and supplemental fixations;

      (2) radiographic assessment of fusion evaluated by an independent radiologist;

      (3) clinical assessment of pain and function using the scales employed in the original IDE study;

   c. use of following mechanisms to inform the patient of the post-approval study and to better assure an adequate number of patients are available at the completion of the study:

      (1) patient agreement to participate in the post-approval study by patient signing Letter of Agreement;

      (2) letters to participating physicians notifying them of impending due dates for patient assessment;

      (3) reimbursement for the physician and/or patient, as necessary;

      (4) reimbursement for costs of x-rays and/or physician office visits by patient's insurance and/or by Spine-Tech, Inc.; and

   d. annual assessment of physician compliance with the study.

2. Because of the unknown long-term device performance, particularly the resulting bony fusion characteristics, please conduct a post-approval study that focusses on the retrieval analyses

of any BAK™ device that is implanted and subsequently removed. This post-approval study is not limited to the patient population described in item 1 above. Histological information (e.g., bony ingrowth quality, bone quantity, response to potential wear debris, etc.) and metallurgical information (e.g., metal wear, deformation, cracking, corrosion, etc.) should be collected and reported in the annual reports. This post-approval study should continue for the duration of the study described in item 1 above.

Please note that the data obtained in these post-approval studies must be reflected in the labeling (via a PMA supplement) when they are completed.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling (i.e., package labels, package insert, patient information brochure, and surgical technique manuals) in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. Mark N. Melkerson, Chief of the Orthopedic Devices Branch at (301) 594-2036.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SUMMARY OF SAFETY AND EFFECTIVENESS

I. GENERAL INFORMATION

DEVICE GENERIC NAME:	Intervertebral Body Fusion Device
DEVICE TRADE NAME:	BAK™ Interbody Fusion System with Instrumentation
APPLICANT'S NAME:	Spine-Tech, Inc. 7375 Bush Lake Road Minneapolis, MN 55439-2029
PREMARKET APPROVAL (PMA) APPLICATION NUMBER:	P950002
DATE OF PANEL RECOMMENDATION:	May 23, 1996
DATE OF NOTICE OF APPROVAL TO THE APPLICANT:	September 20, 1996

II. INDICATIONS FOR USE

The BAK™ Interbody Fusion System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). BAK™ devices are to be implanted via an open anterior or posterior approach.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

III. DEVICE DESCRIPTION

The BAK™ device is a hollow, threaded cylinder available in five sizes. The sizes (diameter x length) are: 13mm x 20mm; 15mm x 20mm; 15mm x 24mm; 17mm x 24mm; and 17mm x 28mm. Each device has 10° modified square threads covering the entire outer surface of the implant and the first 5mm of one end of each device is tapered to allow for easier insertion into a pre-tapped intervertebral cavity. Each device has two large through-holes which are placed cephalad and caudad and multiple small transverse holes to enhance bony ingrowth. The BAK™ device may be used with an optional endcap which is available in corresponding diameters of 13mm, 15mm, and 17mm.

The BAK™ device is manufactured from titanium 6Al-4V (extra low interstitial) alloy which conforms to American Society Testing and Materials (ASTM) F136-92. The endcaps are manufactured from ultra-high molecular weight polyethylene (UHMWPe) which conforms to ASTM F648-84. The BAK™ device and endcap are provided sterile.

The BAK™ device and endcaps are implanted using a defined set of instruments. While some of the instruments are specific to either the anterior or posterior surgical approach, many of the instruments are common between the two surgical approaches. The instruments used for the anterior surgical approach include the following: anterior alignment guide; 8mm drill; distraction plug inserter; distraction plugs; guide pin; slap hammer; drill tube sheath; alignment guide handle; short series spacer; T-handle; starter reamer; final reamer; drill tube sleeve; guide pin; pituitary rongeur; drill tube sheath; trail implant; bone tap; implant driver; and endcap inserter. The instruments used for the posterior surgical approach include the following: starter alignment guide; alignment guide handle; 8mm drill; 8mm drill tube; distraction plug inserter; distraction plugs; drill tube guide; drill tube; guide pin; posterior drill tube sheath; slap hammer; short series spacer; T-handle; starter reamer; guide pin; final reamer; pituitary rongeur; trail implant; bone tap; implant driver; and endcap inserter. All instruments are manufactured from stainless steel which conforms to ASTM F899-94. All instruments are provided nonsterile and must be sterilized prior to use or reuse.

IV. CONTRAINDICATIONS

BAK™ implants should not be implanted in patients with an active infection at the operative site.

V. WARNINGS AND PRECAUTIONS

There are no known warnings associated with the BAK™ Interbody Fusion System.

The surgeon should only implant the BAK™ device after adequate training and familiarity with the surgical technique manual.

Safety and effectiveness have not been established in patients with the following conditions: gross obesity; three or more levels to be fused; symptomatic cardiac disease; pregnancy; previous fusion attempt at the involved level(s); spondylolisthesis or retrolisthesis of Grade II or greater; systemic or terminal illness; significant loss of quantity or quality of vertebral bone stock usually due to osteoporosis or osteomalacia; conditions requiring steroid use; or active drug abuse.

Two devices should be implanted at each surgical level whenever possible. One device may be used if patient anatomy or surgical exposure does not allow for placement of two devices.

The BAK™ implant and endcap are supplied sterile and should be handled in a manner to avoid contamination. In the event of damage to the sterile packaging or inadvertent contamination, implants may be steam sterilized using a gravity cycle of 270°F for 3 minutes. The endcaps should not be re-sterilized if contaminated.

No implant or endcap should be re-used if it has come into contact with human tissue or bodily fluid.

Instruments for implantation of the BAK™ device are provided non-sterile and must be sterilized prior to use. They may be sterilized using gravity steam at 270°F for 10 minutes or 250°F for 15 minutes.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Nonoperative alternative treatments may include, but are not limited to, physical therapy, medications, braces, chiropractic care, or exercise programs. In addition, there are alternative spinal fusion techniques. These include, but are not limited to, posterior lumbar interbody fusion (PLIF) procedures without instrumentation, anterior lumbar interbody fusion (ALIF) procedures without instrumentation, combined anterior and posterolateral (360°) fusion procedures, anterior/anterolateral spinal systems (e.g., plate and screw systems), or posterior spinal systems (e.g., hook and rod systems).

VII. POTENTIAL ADVERSE EFFECTS

From the investigational device exemption (IDE) G900193, a total of 947 patients were evaluated for adverse events with the BAK™ Interbody Fusion System. The adverse events (complications) were stratified by those that did not require surgical intervention and those that did. Further, because not all of the patients entered into the study had reached their 24 month postoperative time point, a time course distribution of the complications was provided. The intervals are as follows: operative (day of surgery); post-operative (first day post-op up to 2 months); 3 month (2 to 5 months); 6 month (5 to 9 months); 12 month (9 to 19 months); and 24 month (19 to 30 months). The overall rate was determined by adding the rates from the operative time point to 24 months. The rates shown in Table 1 below are the patient rates (i.e., number of patients with a particular complication divided by the total number of patients with available data at a given time point).

Table 1 - Complication Rates

	Op. N=947	Post-Op N=947	3 mo N=847	6 mo N=770	12 mo N=661	24 mo N=283	Overall Rate
Complications not requiring surgical intervention							
dura related	3.1%	0%	0%	0%	0.2%*	0%	3.3%
neurologic	1.9%	0.2%	0.4%	0.4%*	0%	0%	2.9%
infection	0%	2.1%	0.2%	0%	0.1%*	0%	2.4%
implant migration	0%	0.3%	0.9%	0.4%	0%	0%	1.6%
ileus	0.4%	1.1%	0%	0%	0%	0%	1.5%
vessel damage, bleeding	1.5%	0%	0%	0%	0%	0%	1.5%

atelectasis, pneumonia	0%	1.2%	0.1%	0%	0%	0%	1.3%
hematoma, seroma	0.1%	1.0%	0.1%	0.1%	0%	0%	1.3%
retrograde ejaculation	0.2%	0.1%	0.7%	0.3%	0%	0%	1.3%
other**	0.1%	0.7%	0%	0.1%	0.1%	0.3%	1.3%
urologic, swollen testicle, prostatic, epididymitis	0.2%	0.6%	0.1%	0%	0%	0%	0.9%
wound dehiscence, incisional hernia	0%	0.4%	0.1%	0.1%	0.1%	0%	0.7%
thrombophlebitis, embolism	0%	0.5%	0.2%	0%	0%	0%	0.7%
leg pain	0.1%	0.1%	0.1%	0%	0%	0.3%*	0.6%
*Complications requiring surgical intervention****							
additional stabilization	0%	0.2%	0.3%	0.6%	1.5%	2.1%	4.7%
additional level fusion	0%	0%	0.1%	0.1%	0.8%	0.7%	1.7%
implant migration	0%	0.6%	0.5%	0.1%	0%	0%	1.2%
leg pain	0%	0.4%	0.1%	0.1%	0.3%	0.3%	1.2%
dura related	0.5%	0%	0.1%	0%	0%	0%	0.6%
implant reposition	0%	0.3%	0%	0.1%	0%	0%	0.4%
other decompression	0%	0.1%	0%	0.1%	0%	0%	0.2%
anterior ligament penetration	0.1%	0%	0%	0%	0%	0%	0.1%
fractured sacrum	0%	0.1%	0%	0%	0%	0%	0.1%

*due to secondary surgical intervention

**other includes: anemia, colitis, gastro-intestinal (GI) bleeding, undisplaced sacral fracture, unrelated sacro-iliac joint infection, chronic subdural hematoma, umbilical hernia (unrelated to surgery), loose implant perioperatively, occipital infarction, possible pre-existing disc space infection

***includes 9 revisions, 7 removals, 27 reoperations, and 26 supplemental fixations (see definitions below)

A revision is a procedure which adjusts or in any way modifies the original implant configuration (e.g., adjusting position of original configuration, removal with replacement of component). A removal is a procedure which removes one or more components of the original implant configuration without replacement of any components. A reoperation is a procedure which involves any surgical procedure at the involved level(s) which does not remove, modify, or add any components. A supplemental fixation is a procedure in which additional instrumentation not approved as part of the protocol is placed. This may include supplemental placement of a rod/screw system or a plate/screw system.

VIII. MARKETING HISTORY

The BAK™ Interbody Fusion System has been marketed in approximately 20 international countries. It has not been withdrawn from marketing for any reason relating to its safety or effectiveness.

IX. SUMMARY OF PRECLINICAL STUDIES

A. Nonclinical Testing

Nonclinical tests were conducted to characterize the mechanical properties of the BAK™ Interbody Fusion System. The smallest size BAK™ device (13mm x 20mm) was used for this testing because it represents the worst case device (thinnest internal web and thinnest cylindrical wall thickness) of the five sizes.

1. Ultimate Compressive Strength Testing

A single BAK™ device was loaded statically in compression until implant failure or until 30,600 N (6876 lbs), the failure load of the jig, was reached. Five (5) devices sustained a static load of 30,600 N (6876 lbs) without failure. None of the five specimens were crushed or exhibited any cracking under microscopic examination following the testing. The device's compressive strength greatly exceeds the compressive strength of bone which is estimated to be approximately 1500 N (337 lbs).

2. Fatigue Testing

A single BAK™ implant was loaded cyclically in compression at loads which ranged from 880 N (198 lbs) to 9600 N (2157 lbs) at 15 Hz. None of five (5) devices failed after 5 million cycles. Five million cycles typically represents the number of loading cycles a device might experience within two years. This assumes moderate loading and the device's goal of stabilizing until fusion occurs within those two years. Because the device's compressive fatigue strength exceeds the static compressive strength of bone by at least a factor of six, the

BAK™ device can be expected to withstand anticipated physiologic fatigue loads.

3. Polyethylene Endcap Pushout Test

This test was conducted to determine the static force required to dislodge the endcap from a BAK™ device. After the endcap was snap-fit to the BAK™ device, an axial load was applied through the cavity of the BAK™ device to the endcap. The average push-out load determined for five (5) samples was 111 ± 53 N (25 ± 12 lbs). Based on the expected minimal loading on the endcap, the endcap should not become dislodged from the BAK™ device.

B. **Stability Testing**

Three tests were performed to determine the effect of the device on the flexion/extension (F/E) and lateral stability of the spine after implantation of either one or two BAK™ devices. Bovine, porcine, and primate spines were used in these tests.

1. The first test was conducted to determine the effect of implanting one and two BAK™ devices on spinal stability, relative to the intact spine. One BAK™ device was implanted in a bovine spine (n=7) and two BAK™ devices were implanted in a porcine spine (n=2) and the flexion/extension and lateral stiffness of the spines were measured. Results with one device implanted showed that the spinal segments had an increased stiffness of 71% for flexion/extension and 77% for lateral bending relative to the same tests in spinal segments without implants. Results with two devices implanted showed that the spinal segments had an increased stiffness of 81% for flexion/extension and 477% for lateral bending relative to the same tests in spinal segments without implants. Therefore, the implantation of either one or two devices increased the initial spinal stability.

2. The second test was designed to compare the initial biomechanical stability of the following constructs in a calf spine model: 1) BAK™ implant; 2) PLIF with iliac crest bone graft alone; 3) PLIF with rigid posterior instrumentation; 4) BAK™ implant with rigid posterior instrumentation; and 5) rigid posterior instrumentation (pedicle screws). Non-destructive testing was performed on eight (8) lumbar (L3-L4) calf spines of similar age and size. Each specimen was tested for stiffness in flexion/extension, torsion, and axial loading using the intact spine as a baseline and the five constructs above.

The BAK™ system, used alone, doubled the stiffness of the intact spine in terms of flexion/extension loading (2.6 versus 1.3 Nm/deg) and torsional loading (14 versus 7.5 Nm/deg) and did not migrate during testing. This BAK™ construct was stiffer than the PLIF with iliac crest bone graft alone (which had a flexion/extension stiffness of 1 Nm/deg and a torsional stiffness of 5 Nm/deg) and was similar in stiffness to the PLIF with rigid posterior instrumentation (which had a flexion/extension stiffness of 2.9 Nm/deg and a torsional stiffness of 12.5 Nm/deg). The BAK™ increased the initial stiffness of a calf spine motion

segment relative to the intact spine and compares favorably to the other stabilization methods with respect to initial spinal stability.

3. The third test assessed the mechanical flexibility of the motion segment both before and after instrumentation using the BAK™ device in a Chagma baboon model. Testing was performed on six (6) Chagma baboon spines at the L4-L5 motion segment. Each specimen was tested for stiffness in flexion and extension in its intact condition and with a single BAK™ implant. The six (6) instrumented lumbar segments showed a trend for increased stiffness in flexion ($p<0.07$). In the four comparisons made in extension, the instrumented segments were stiffer ($p<0.05$). The BAK™ device increased the flexion/extension stiffness of the spine relative to the intact spine.

C. Foraminal Volume Study

The objective of this study was to quantitatively assess changes in the size of the neuroforamen after anterior distraction using the BAK™ Interbody Fusion System in degenerated cadaveric lumbar spines. Nine (9) fresh frozen degenerative cadaver lumbar spines were obtained for the study. Anteroposterior and lateral x-rays were taken for each specimen with neuroforaminal stenosis at L4-L5 and L5-S1. The lateral x-rays were used to measure the anterior and posterior disc heights before and after insertion of the BAK™ implants. Measurements of the volumes and areas were conducted before and after anterior application of the BAK™ implants using three techniques: blunt probe; silicone mold; and computerized tomography. All data were normalized to the pre-implantation measurements.

After BAK™ implantation, the anterior disc heights increased 35.2 ± 19.2% at L4-L5 and 28.4 ± 12.0% at L5-S1 ($p<0.001$); the posterior disc heights increased 37.1 ± 20.9% at L4-L5 and 45.1 ± 28.0% at L5-S1 ($p<0.001$). The neuroforamen diameters measured with the blunt probe increased 13.3 ± 4.1% at L4-L5 and 12.3 ± 4.3% at L5-S1 after the BAK™ implantation. The areas measured by CT increased 29.0 ± 18.6% at L4-L5 and 33.8 ± 22.2% at L5-S1 after BAK™ implantation. The volume of each neuroforamen was calculated from the mass of the silicone mold and material density. The volumes increased 22.9 ± 8.3% at L4-L5 and 21.5 ± 11.5% at L5-S1. These results indicate that the BAK™ implant can increase the neuroforaminal volume and possibly reduce neuroforaminal stenosis.

X. SUMMARY OF ANIMAL STUDIES

A. Horse Studies

Studies involving the Bagby Basket, a smooth, stainless steel cylinder with transverse holes, as an interbody fusion device were conducted.

1. The first study involved the use of the Bagby Basket in stabilizing equine cervical vertebra. The goal of this study was to compare commercially available xenograft

with the Bagby Basket filled with local autograph bone for equine interbody fusion. 16 horses were assigned into one of two treatment groups, eight (8) received a dowel of bovine xenograft and eight (8) received the Bagby Basket. At six months postoperatively, the horses were sacrificed and the spines evaluated.

Mobility studies produced an index value for evaluation of both treatment groups. The index value of the implant was representative of substantially less perceptible motion than the index of the grossly fibrous bovine xenografts. Implantation of the bovine xenograft and the implant resulted in different forms of vertebral fusion. The use of the implant with autogenous bone graft usually resulted in an osseous union and provided a superior fusion. Gross examination of the fusion sites on cut section revealed several differences. The sites in which bovine xenografts had been implanted were extremely pale and frequently contained gross evidence of fibrous connective tissue dispersed through the graft sites. There was minimal evidence of fibrous connective tissue dispersed through the Bagby Basket implantation sites. The autograft within the implant was more consistent with the color and texture of normal cancellous bone.

2. A second study was conducted to evaluate the clinical effectiveness of the Bagby Basket in decompressing caudal cervical spinal cord compression in the horse. In this test, eight (8) male horses with caudal cervical spinal cord compression were implanted with a single bone graft-filled Bagby Basket in an effort to fuse the intervertebral space at the level of compression. The horses were evaluated five months postoperatively by neurologic evaluation, radiology, myelography, CSF analysis, serology, virology and bacteriology. Neurologic exams were repeated 10 months postoperatively. This test showed that all of the implants appeared to have been incorporated in osseous arthrodesis and that this was effective in decompressing all horses by five months post-op. All other results (CSF analysis, serology, virology, and bacteriology) were normal, both preoperatively and postoperatively.

B. **Primate Study**

This study was undertaken to evaluate the safety and effectiveness of the BAK™ device when used in the Chagma baboon. The effectiveness in producing a stable lumbar interbody construct was measured by radiologic, biomechanics, and histologic methods.

Comparing the BAK™ device and fresh frozen allograft in this experimental model, it was found that: 1) the Chagma baboon is an adequate model in evaluating lumbar interbody fusion techniques; 2) radiologic assessment showed that disc height loss and increased local kyphosis occurred over time in both groups, although the allografts stabilized earlier (6 weeks) compared to the BAK™ device (24 weeks); 3) biomechanical evaluation revealed no statistically significant differences between the two implant groups; 4) histologic findings confirmed bone ingrowth in the BAK™ group; and 5) the BAK™ Interbody Fusion System was found to be an adequate fusion technique compared to fresh-frozen allograft in this experimental model and justified further human clinical assessment.

XI. SUMMARY OF CLINICAL INVESTIGATIONS

A clinical study of the BAK™ Interbody Fusion System was conducted in accordance with approved IDE G900193.

A. Objective

The objective of the study was to determine the safety and effectiveness of the BAK™ Interbody Fusion System in stabilizing and fusing the affected vertebrae when compared to literature controls.

B. Inclusion and Exclusion Criteria

The inclusion criteria were males and females between the ages of 21 and 65 with a diagnosis of DDD at 1 or 2 contiguous levels from L2-S1. These patients may have had disc herniation and/or no greater than Grade I spondylolisthesis. Additionally, these patients were to have had six months of unresponsive, nonoperative treatment. Note that based on Panel input, the definition for DDD was refined to that reflected in Section II above, Indications for Use.

The exclusion criteria were as follows: patients with active infection; osteoporosis or osteomalacia; a medical condition that interfered with the postoperative management program; circulatory problems; symptomatic cardiac disease; active malignancy; gross obesity; Grade II or greater spondylolisthesis at involved spine levels; pregnancy; DDD affecting three or more spine motion segments; and the presence of more three of the following psycho-social factors: alcoholism; drug dependence; recent or pending divorce; high level of job dissatisfaction; pending litigation; depression; multiple unsuccessful surgeries; smoking one or more packs per day; or a Waddel score of three or more.

Patients meeting the inclusion criteria were stratified into four treatment groups by the surgical approach (i.e., open anterior or open posterior) and the number of involved levels (i.e., one or two).

- Anterior surgical approach involving one disc level (A1)
- Anterior surgical approach involving two disc levels (A2)
- Posterior surgical approach involving one disc level (P1)
- Posterior surgical approach involving two disc levels (P2)

For both surgical approaches, autogenous bone graft was packed into the BAK™ devices after implantation. If the disc space had sufficient room after devices placement, autogenous bone graft could be placed around them.

C. Patient Population and Demographics

The BAK™ study population is comprised of 54% (512/947) males and 46% (435/947) females. The mean age at the time of study enrollment was 41.5 years with a range of

20 to 73 years. 57% (544/947) of the patients were enrolled in the study with compensation related injuries. 36% (342/947) of the patients had prior back surgery. The average duration of back symptoms prior to enrollment in this study was 5.5 years.

All 947 patients enrolled in the BAK™ study had a diagnosis of DDD, 43% (408/947) with disc herniation and 57% (539/947) without herniation. Grade I spondylolisthesis or retrolisthesis (reverse spondylolisthesis) was present in 12% (112/947) of the population.

A total of 1317 levels were implanted in 947 patients. The distribution of the levels by patient were: <1% (5/947) at L2-L3; 5% (49/947) at L3-L4; 56% (530/947) at L4-L5; 38% (356/947) at L5-S1; <1% (4/947) at L5-L6; <1% (1/947) at L6-S1; and <1% (2/947) at L6-S1. Of the 947 patients, 62% (591/947) had one-level fusions and 38% (356/947) had two-level fusions. There were 55 single cages and 1262 pairs of cages implanted for a total of 2579 cages implanted.

D. **Evaluation Schedule**

Patients were evaluated preoperatively, immediately postoperatively (i.e., hospital discharge), at 3 months, 6 months, 12 months, 24 months, and biennially thereafter until the last patient had his/her two-year evaluation. Radiographic studies were conducted at 12 and 24 months postoperatively.

E. **Patient Accountability**

A total of 947 patients were enrolled at 19 investigational sites in the United States by 44 investigators. Of these 947 patients, there were 32% (305/947) in the A1 subgroup, 30% (286/947) in the A2 subgroup, 29% (272/947) in the P1 subgroup, and 9% (84/947) in the P2 subgroup. As of November, 1995, a total of 307 patients had reached his/her two-year postoperative time point. Follow-up evaluations, which included an assessment of fusion, pain, function and muscle strength, were performed on 283 of these 307 patients (92%). Complete follow-up evaluations (i.e., measurement of each of the four major outcome parameters) were performed on 254 of these 283 patients (90%). Partial follow-up evaluations were available for 29 patients (10%).

F. **Study Design and Analyses**

1. Literature Study Control

Literature controls were employed in this study. Outcomes of patients implanted with BAK™ devices via an anterior approach were compared to outcomes of patients who received ALIFs. Outcome of patients implanted with BAK™ devices via a posterior approach were compared to outcomes of patients who received PLIFs. Literature references were deemed acceptable as controls if at least 50% of patients had back pain due to DDD; this group may or may not have had spondylolisthesis of Grade I or less. This differs from the BAK™ group in which all patients had back pain due to DDD and had no greater than Grade I

spondylolisthesis.

The literature controls used in this study had many differences relative to the BAK™ population with respect to the indication for use, the method by which DDD was assessed, the number of levels fused, the age of the patients, the types of outcome criteria assessed, the method of outcome assessment, the definitions for successful outcome, the duration and nature of follow-up, the incidence of previous back surgery at the same level, and whether the patients were affected by more than two psychological/behavioral risk factors (e.g., alcoholism, drug abuse).

Use of a literature control group was common at the time of the submission of this study, although it is now recognized as less desirable than a randomized, concurrent control study. The advantages of using a randomized, concurrent control reflects the disadvantages of literature controls. In general, in a randomized, concurrent control study, potential bias is eliminated or at least reduced, unknown or known baseline factors tend to be balanced between the two groups, the statistical properties of hypothetical tests are improved, time trends are controlled because of concurrency, and the results tend to be more successfully convincing.

2. Data Pooling

Pooling the data between investigational sites and other stratified groups were justified based on a statistical analyses using Pearson chi-squared tests or Fishers exact tests.

G. Effectiveness Analyses

The effectiveness variables included an assessment of fusion at the involved level(s), pain, function, and muscle strength; neurological information was captured in the safety assessment. In some cases, only partial data were available (i.e., not all of the four outcome measures were obtained for all patients at all follow-up points). In these cases, all available outcomes for fusion, pain, function, and muscle strength were summarized in these analyses. Therefore, the number of patients included in the assessment of the four outcomes varies slightly due to missing data. Because not all of the patients had reached his/her two-year postoperative time point, the effectiveness analyses involved both the 12 month and 24 month time points for comparison purposes.

H. Effectiveness Analysis - Fusion

Successful fusion was defined as less than 5° of motion on a flexion/extension series of x-rays at the involved level(s). In cases where two levels were implanted, both levels must have been fused in order for that patient to be considered fused. An independent radiologist reviewed the films. The successful fusion rates are provided in Table 2 below for each study subgroup and the overall population.

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Table 2 - Successful Fusion Rates at 12 and 24 Months

Study Subgroups	12 Month Rate	24 Month Rate
Anterior, 1-level	92% (211/229)	98% (106/108)
Anterior, 2-levels	79% (118/150)	80% (56/70)
Posterior, 1-level	87% (156/180)	94% (68/72)
Posterior, 2-levels	75% (45/60)	71% (12/17)
All Study Subgroups	86% (530/619)	91% (242/267)

I. Effectiveness Analysis - Pain

Pain was measured on a 6-point scale where 1 = no recurrent episode of low back pain and able to perform all previous activities, 2 = occasional recurrence of low back pain, 3 = mild pain, 4 = moderate pain, 5 = marked pain, and 6 = disabling pain.

The distribution of pain scores preoperatively and at 24 months is shown in Table 3 below. One patient was missing the preoperative pain score.

Table 3 - Distribution of Pain Scores

Pain Level	Preoperative Rate	24 Month Rate
None (1)	0%	19% (54/280)
Episodic (2)	<1% (4/946)	18% (49/280)
Mild (3)	<1% (6/946)	27% (75/280)
Moderate (4)	22% (210/946)	24% (68/280)
Marked (5)	54% (506/946)	9% (25/280)
Disabled (6)	23% (220/946)	3% (9/280)

All patients experiencing an improvement by at least one level in the pain score relative to their preoperative score were considered to have a successful result in terms of the pain outcome measure. Table 4 below shows the successful pain rates for each study subgroup and the overall population.

Table 4 - Successful Pain Rates at 12 and 24 Months

Study Subgroups	12 Month Rate	24 Month Rate
Anterior, 1-level	84% (202/240)	84% (93/111)
Anterior, 2-levels	88% (136/155)	86% (62/72)
Posterior, 1-level	81% (158/196)	87% (66/76)
Posterior, 2-levels	77% (48/62)	81% (17/21)
All Study Subgroups	83% (544/653)	85% (238/280)

It is important to distinguish between patients with a successful pain outcome and the amount of pain experienced by patients after implantation with the BAK™ device. A successful outcome did not necessarily mean that a patient experienced no pain; instead, it means that there was at least one level of improvement.

J. Effectiveness Analysis - Function

Function was measured on a 26-point scale which ranged from 7 (best) to 32 (worst) points. This function scale measures the patient's ability to perform activities of daily living (i.e., standing, sitting, walking, squatting, ability to put on shoes and socks), level of recreational activity, and level of employment.

The average preoperative function score was 20.9 ± 3.7 (range 9-32) for 946 patients; a preoperative function score was missing for one patient. The average function score at 24 months was 14.5 ± 4.5 for 280 patients.

All patients maintaining or experiencing an improvement by at least one point in the function score relative to their preoperative score, were considered to have a successful result in terms of the function outcome measure. Table 5 shows the successful function rates for each study subgroup and the overall population.

Table 5 - Successful Function Rates at 12 and 24 Months

Study Subgroups	12 Month Rate	24 Month Rate
Anterior, 1-level	93% (224/240)	95% (105/111)
Anterior, 2-levels	89% (138/155)	94% (68/72)
Posterior, 1-level	89% (174/196)	92% (70/76)
Posterior, 2-levels	89% (55/62)	95% (20/21)
All Study Subgroups	91% (591/653)	94% (263/280)

K. Effectiveness Analysis - Muscle Strength

Muscle strength was evaluated bilaterally at four sites: quadriceps, dorsiflexion-inversion, great toe extension, and plantarflexion. Each of the sites was measured an a 3-point scale ranging from 1 (normal) to 3 (marked decrease). The majority of patients (82%) demonstrated normal muscle strength preoperatively.

Maintenance or improvement in muscle strength for all eight sites evaluated was required to be considered a success. Table 6 shows the successful muscle strength rates for each study subgroup and the overall population.

Table 6 - Successful Muscle Strength Rates at 12 and 24 Months

Study Subgroups	12 Month Rate	24 Month Rate
Anterior, 1-level	92% (221/240)	94% (102/109)
Anterior, 2-levels	92% (135/147)	94% (64/68)
Posterior, 1-level	95% (176/185)	94% (67/71)
Posterior, 2-levels	92% (55/60)	100% (20/20)
All Study Subgroups	93% (587/629)	94% (253/268)

L. Safety Analysis

Safety analyses included all patients regardless of the completeness of their follow-up data or length of follow-up. Safety was assessed through physical examinations, x-rays, and by questioning of all patients enrolled in the study. For a summary of the safety data, please see Table 1 in Section VII above, Potential Adverse Effects.

M. Study Success / Statistical Differences

To be considered an overall study success, the patient must have met each of the following four criteria: 1) fusion of the involved level(s); 2) improvement in pain; 3) maintenance or improvement in function; and 4) maintenance or improvement in muscle strength. The overall success rates at 12 and 24 months for each subgroup and the overall patient population are provided in Table 7 below. Note that the number of patients with data available differs slightly for each based on the study follow-up.

Table 7 - Study Success Rates at 12 and 24 Months

Study Subgroups	12 Month Rate	24 Month Rate
Anterior, 1-level	73% (163/223)	81% (85/105)
Anterior, 2-levels	64% (90/140)	59% (39/66)
Posterior, 1-level	64% (108/168)	78% (52/67)
Posterior, 2-levels	52% (30/58)	50% (8/16)
All Study Subgroups	66% (391/589)	72% (184/254)

The clinical utility of the BAK™ procedure also was evaluated by the proportion of patients that returned to work or were able to work. At the time of the initial BAK™ procedure, 36% of all patients were working full-time or part-time. The proportion of patients working was decreased to 30% at three months follow-up and then progressively increased to 44%, 54%, and 62% at 6, 12, and 24 month follow-up visits, respectively.

Because of the many differences between the literature control groups and the BAK™ group, the longitudinal analyses performed on the BAK™ patient population was extremely important in the assessment of the safety and effectiveness of the BAK™ device. The longitudinal analyses (using Generalized Estimating Equation (GEE) model) showed that the outcomes of fusion, pain, function, and muscle strength did not worsen over time for all study subgroups combined. Specifically, for the total patient population, the rate of fusion increased with time, the amount of pain decreased with time, and the patient's ability to function increased with time.

From the longitudinal analyses of these clinical data, the following statistical differences were observed among the study subgroups up to or at the two-year time point:

- The two year postoperative data indicates that the likelihood of needing additional supplemental fixation increases over time in patients who were not fused or showed no improvement in pain.

- For both the anterior and posterior approaches, patients with one level fusion had lower overall complication rates than patients with two level fusions.

- Patients implanted with the BAK™ device from the posterior approach had higher rates of intra-operative complications and early postoperative surgical interventions than patients implanted from the anterior approach.

- Patients implanted from the anterior approach had a higher overall rate of early postoperative complications than patients implanted from the posterior approach.

- For both the anterior and posterior approaches, patient who had higher preoperative baseline pain scores showed better pain improvement throughout the study than patients with lower baseline pain scores.

N. Comparison with Literature Controls

A total of 20 ALIF and 9 PLIF literature articles were used as controls; these are identified in Section XVI below, References. As previously discussed, these literature controls were often greatly different from the BAK™ population. However, clinical results and complication information were extracted for purposes of this comparison.

1. Anterior Results

As stated above, there were 20 ALIF literature control articles. The sample sizes reported in these articles ranged from 20 to 150. The data from the control articles were compared to the data from the BAK™ Interbody Fusion System for the total anterior patient population (i.e., A1 and A2) at 24 months.

The fusion rate for the BAK™ was 91% (162/178) for the anterior group. The range of fusion rates reported in the ALIF literature controls was 46% to 96%. Fusion results of the BAK™ were better than literature results in 18 of 20 articles, significantly better in 13, and none were significantly worse than the literature controls.

The definition of clinical success in the ALIF literature primarily involved an assessment of pain but occasionally included some work status, function, and narcotic use information. The clinical success rates reported in the ALIF literature ranged from 41% to 100%. Taking into consideration the same types of measurements, these literature control rates were compared to the following BAK™ clinical rates: 85% (155/183) for pain and 95% (173/183) for function. There were 22 possible assessments in the 20 ALIF literature controls. BAK™ clinical results were better than ALIF in 8 assessments, within 5% of the ALIF results in 3 assessments, and worse than the ALIF results in 11 assessments. It cannot be determined if the differences are due to true differences in clinical success, or due to differences in patient population, data collection, or interpretation of methods.

2. Posterior Results

As stated above, there were 9 PLIF literature control articles. The sample sizes reported in these articles ranged from 20 to 462. The data from the control articles were compared to the data from the BAK™ Interbody Fusion System for the total posterior patient population (i.e., P1 and P2) at 24 months.

The fusion rate for the BAK™ was 90% (80/89) for the posterior group. The range of fusion rates reported in literature was 74% to 96%. Fusion results for the

BAK™ device were higher than 5 PLIF studies and statistically higher in 1. Although 4 of the PLIF studies reported results better than the BAK™, none of these differences were statistically significant. It is unclear if these differences are due to true differences in clinical success or due to differences in patient population, data collection or interpretation of methods.

As with the ALIF literature, the definition of clinical success in the PLIF literature primarily involved an assessment of pain but occasionally included some work status, function, and narcotic use information. The clinical success rates reported in the PLIF literature ranged from 60% to 94%. Taking into consideration the same types of measurements, these literature control rates were compared to the following BAK™ clinical rates: 86% (83/97) for pain and 93% (90/97) for function.

3. Comparison of Complications

The experience in this clinical investigation with the BAK™ system compares favorably with the ALIF and PLIF literature complication rates. Reported complications for the BAK™ system were within the range reported for the literature control groups.

XII. CONCLUSIONS DRAWN FROM THE STUDIES

The nonclinical (i.e., mechanical), animal, and clinical data provide reasonable assurance of the safety and effectiveness of the BAK™ Interbody Fusion System for the treatment of degeneration disc disease (DDD), when used as indicated.

XIII. PANEL RECOMMENDATION

The Orthopedic and Rehabilitation Devices Panel met to discuss the application on May 23, 1996. The Panel recommended that the application be approved pending submission to and approval by the Center for Devices and Radiological Health (CDRH) of: a reanalysis of the study outcomes with a revised definition of patient success; modifications to the labeling; creation of a patient information document; development of post-approval studies; continued follow-up of study patients; and completion of the IDE randomized study arm of the BAK™ Interbody Fusion System. The Panel agreed with FDA's recommendation to define patient success as fusion of involved level(s); improvement in pain; maintenance or improvement in function; maintenance or improvement in muscle strength; and maintenance or improvement in neurological reflexes.

The Panel recommended that the labeling be modified to: (1) limit use to the treatment of patients with DDD where DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by historical and radiographic studies; (2) recommend a minimum of six months of non-operative treatment prior to surgery; (3) report the study's success rates and trends noted in the statistical analyses; (4) require that the device be packed with autograft bone; (5) limit implantation of the device to an open

approach; and (6) limit use of the device to fusions involving one level or two adjacent levels.

As stated above, the Panel also recommended that two post-approval studies be developed. The first post-approval study is to obtain continued follow-up for a subset of the patients from the IDE study to evaluate the long-term device performance and patient outcomes for a minimum of five years. The second post-approval study is to retrieve and analyze any BAK™ device that was implanted and subsequently removed. The Panel recommended that retrieved implants be analyzed metallurgically and histologically for bone quality/quantity and potential wear debris.

XIV. CDRH DECISION

CDRH agreed with the Panel's recommendation that the PMA be approved subject to conditions and concurred with each of the conditions recommended by the Panel except for the recommendations to require continued follow-up of study patients and completion of the IDE randomized study arm of the BAK™ Interbody Fusion System. While CDRH agreed that it would be desirable to obtain long-term follow-up on the entire study population and the results of a randomized, concurrent clinical trial of the BAK™ device, sufficient information currently exists to approve this application. The Panel's recommendations were modified and made conditions of approval. In addition to the Panel's recommended conditions, CDRH also required the following information: a time course distribution of the complications; revision of the labeling to incorporate all applicable changes (e.g., indications for use, clinical results, complications); inclusion of sterilization instructions for the instrumentation in the labeling; modifications to the surgical technique manuals; generation of a surgeon training program; and development of the post-approval studies with specific elements.

FDA issued a letter to Spine-Tech, Inc. on June 20, 1996, advising that its PMA was approvable subject to the conditions listed above as recommended by the Panel and required by FDA.

In amendments received by FDA on July 26, August 12, and August 23, 1996, Spine-Tech, Inc. submitted the requested information. The company reanalyzed the clinical outcomes using the revised definition of overall patient success (redefined again to be based on only fusion, pain, function, and muscle strength while capturing neurological information in the complication section), provided the time course distribution of complications, revised the labeling, described their surgeon training program, and developed two post-approval studies. The first post-approval study involves the collection of clinical and radiographic data for long term device performance and patient outcomes for an additional four years of follow-up (for a total of six years of postoperative data) on a subset of the IDE patient population; the goal is to obtain six years of postoperative data on a minimum of 100 patients per surgical approach. The second post-approval study involves the retrieval assessment of any BAK™ device that is implanted and subsequently removed.

In amendments received by FDA on September 11 and September 13, 1996, Spine-Tech, Inc. submitted the required information which included revisions to the labeling and post-approval studies and agreed to the conditions cited in the approvable with conditions letter dated June 20, 1996. CDRH determined that, based on the above modifications, the applicant's response was adequate.

FDA inspections completed on August 6 and 7, 1996, determined the manufacturing facilities to be in compliance with the Good Manufacturing Practices (GMP) regulations.

CDRH issued an approval order on _____.

XV. APPROVAL SPECIFICATIONS

Directions of Use: See labeling.

Hazards to Health from Use of the Device: See indications, contraindications, warnings, precautions, and adverse events in labeling.

Post-approval Requirements and Restrictions: See approval order.

XVI. REFERENCES FOR CONTROLS

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BAK INTERBODY FUSION SYSTEM
PATIENT INFORMATION BROCHURE

Introduction
This Patient Information Brochure is to help you make an informed decision about your back surgery, specifically with the BAK Interbody Fusion System.

What is the BAK System
The BAK Interbody Fusion System consists of implants and optional endcaps. The implants are made from titanium alloy and the endcaps from polyethylene. Both of these materials are compatible with the human body. The implants are similar to large, hollow screws with holes in them and are usually implanted in pairs in the disc space (cushion between the vertebrae of the spine). The implants are filled with bone taken from the patient's hip.

Which Patients Might Benefit From the BAK System
In your lower back there are five vertebrae (bones). Between each of the vertebra is a disc which is a cushion-like material. Motion occurs through the disc. Your disc can wear down and cause pain.

Based on your examination, your doctor has asked you to consider a spinal fusion procedure with the BAK Interbody Fusion System because you have a condition called "degenerative disc disease" (DDD). This results in pain coming from the disc. The purpose of this surgery is to stabilize and fuse one or two disc spaces of your spine and relieve your back pain.

Although your doctor is planning to use the BAK Interbody Fusion System for your condition, you should be aware that there are alternative treatments to this type of device. If you want information on these options, please discuss them with your doctor.

As a note, the BAK Interbody Fusion System is approved for patients with degenerative disc disease. The BAK implant is filled with bone from your hip and may be implanted from the second lumbar disc (L2) down to the sacrum. Only one or two disc spaces are to be fused. These patients with DDD may also have limited slippage of one vertebra over the vertebra below it (Grade I spondylolisthesis). Patients should be skeletally mature and should have had six month of non-operative treatment.

Above describes which patients should receive the BAK Interbody Fusion System. You should also be aware that the BAK Interbody Fusion System should not be used in patients with severe infection.

In addition, you should be aware that there was little data or no data for patients with gross obesity, symptomatic cardiac disease, pregnancy, three or more levels to be fused, excessive forward or backward vertebral slippage, major illness, significant loss of quantity or quality of vertebral bone, condition requiring steroid use, active drug abuse, or had a previous fusion attempt at the same disc space. If you have any of these conditions, please discuss the issue with your doctor.

The BAK Surgery
Portions of the disc and bone are drilled out and the BAK implants are screwed into the holes. Bone graft is placed inside and between the BAK implants so that the bone may grow through the implants, fusing the disc space. The BAK Interbody Fusion System is implanted from the front (anterior) or back (posterior) surgical approach. Your doctor will make this decision depending on your condition.

After Surgery
You will be expected to be seen by your doctor several times after surgery to evaluate your pain and function. X-rays will be taken to check the BAK implants. You should ask your doctor about

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7375 Bush Lake Road
Minneapolis, MN 55439-2029
1-800-655-2614

September 19, 1996

his/her postoperative rehabilitation program and follow-up plan. It is important to follow your doctor's instructions carefully in order to recover from your surgery as quickly as possible.

Possible Complications

Complications related to spinal implant surgery include, but are not limited to, the following: tear in the outer lining of the spinal cord (dura), spinal fluid leak, nerve complications, infection, slow movement of the intestines (ileus), implant migration, blood vessel damage/bleeding, leg pain, bruise (hematoma), pneumonia, retrograde ejaculation into bladder, fractured sacrum, blood clots, wound closure problems and bladder problems.

Information on rates of specific complications may be discussed with your doctor. Your doctor may refer to the package insert that was provided to him/her for a list of complication rates observed in the clinical study discussed below.

Clinical Results

A clinical study of the BAK System was conducted at a number of hospitals. There were a total of 283 patients with available data at two years. The success rates are shown below for overall success and for each major individual measure of success. The patients who were an overall success had successful results in all four of the major measurements (fusion, pain, function and muscle strength). As you can see, the results were separated by the type of surgical approach and number of disc spaces fused.

	Anterior		Posterior	
	1	2	1	2
Overall Success	**81%**	**59%**	**78%**	**50%**
Fusion Rate	98%	80%	94%	71%
Pain Improvement	84%	86%	87%	81%
Function Maintained or Improved	95%	94%	92%	95%
Strength Maintained or Improved	94%	94%	94%	100%

Note that the number of patients used to calculate the success rates were slightly different for each of the measurements above due to unavailable data. Please talk to your doctor if you have questions regarding this clinical information or about the statements in the following section.

Based on this clinical study, the following statements may be made about the BAK system.

- The two year data indicates that the likelihood of needing additional supplemental fixation increases over time in patients who were not fused or showed no improvement in pain.
- For both the anterior and posterior approaches, patients with one disc space fused had lower overall complication rates than patients with two disc spaces fused.
- Patients implanted with a BAK device from the posterior approach had higher rates of operative complications and early postoperative surgical interventions than patients implanted from the anterior approach.
- Patients implanted from the anterior approach had a higher overall rate of early postoperative complications than patients implanted from the posterior approach.
- For both the anterior and posterior approaches, patients who had higher preoperative pain scores showed better pain improvement throughout the study than patients with lower preoperative pain scores.

Your doctor's experience may be similar to or different than the findings listed above. It is your choice to have a spinal fusion using the BAK implants. Please ask your doctor any questions you have so that you will make a decision that is best for you.

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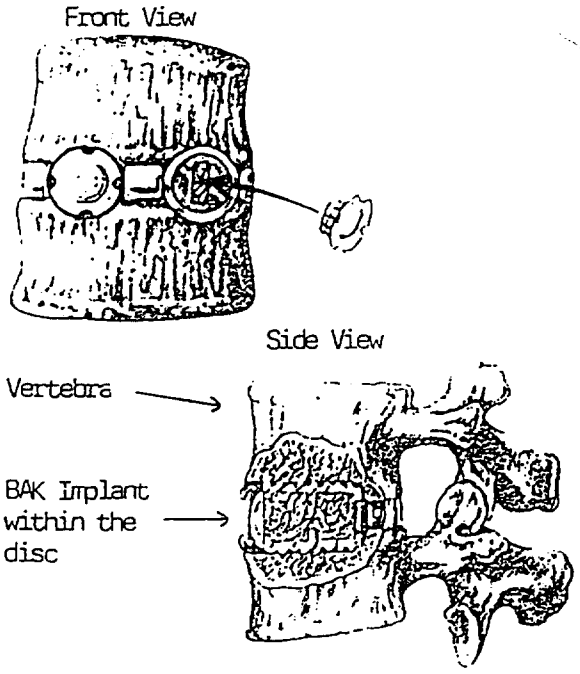
September 19, 1996

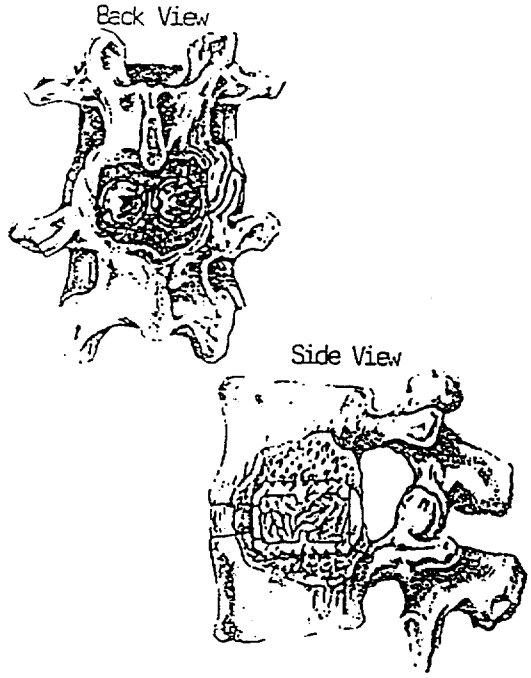
BAK INTERBODY FUSION SYSTEM
PATIENT INFORMATION BROCHURE

Questions

If you have any questions or need additional information, please contact your doctor.



BAK Implants shown using the anterior (front) approach



BAK Implants shown using the posterior (back) approach

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BAK INTERBODY FUSION SYSTEM

Description

The BAK Interbody Fusion System consists of BAK Interbody implants and BAK endcaps. The BAK implant is available in five sizes (diameter x length): 13mm x 20mm, 15mm x 20mm, 15mm x 24mm, 17mm x 24mm and 17mm x 28mm. The BAK implant may be used with an optional endcap which is available in corresponding diameters of 13mm, 15mm and 17mm.

The BAK implants are made from titanium alloy (Ti-6Al-4V), conforming to ASTM F136. The endcaps are made from ultra-high molecular weight polyethylene (UHMWPE), conforming to ASTM F648. Instruments designed for implantation of the BAK device are made from stainless steel, conforming to ASTM F899. These instruments are identified in the Surgical Technique Manual.

Indications

The BAK device is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). BAK devices are to be implanted via an open anterior or posterior approach.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Contraindications

BAK devices should not be implanted in patients with an active infection at the operative site.

Precautions

The surgeon should only implant the BAK device after adequate training and familiarity with the surgical technique manual.

Safety and effectiveness have not been established in patients with the following conditions: gross obesity, three or more levels to be fused, symptomatic cardiac disease, pregnancy, previous fusion attempts at the involved level(s), spondylolisthesis or retrolisthesis of Grade II or greater, systemic or terminal illness, significant loss of quantity or quality of vertebral bone stock usually due to osteoporosis or osteomalacia, a condition requiring steroid use or active drug abuse.

Two devices should be implanted at each surgical level whenever possible. One device may be used if patient anatomy or surgical exposure does not allow for placement of two devices.

The BAK implant and endcap are supplied sterile and should be handled in a manner to avoid contamination. In the event of damage to the sterile packaging or inadvertant contamination, implants may be steam sterilized using a gravity cycle of 270 degrees F for 3 minutes. The endcaps should not be re-sterilized if contaminated.

No implant or endcap should be re-used if it has come in contact with human tissue or bodily fluid.

Instruments for implantation of the BAK device are provided non-sterile and must be sterilized prior to use. They may be sterilized using gravity steam at 270 degrees F for 10 minutes or 250 degrees F for 15 minutes.

Adverse Effects

The following adverse effects were reported during a multi-center clinical study of 947 patients implanted with the BAK device. These adverse effects were recorded and classified as operative and postoperative. The rates presented are the number of patients with a particular complication divided by the total number of patients with available data at a given time period. Anterior and posterior complications are combined.

Printed: 9/19/96

Complications Over Time

	Operative % N=947	Post-Op % N=947	3 Month % N=847	6 Month % N=770	12 Month % N=661	24 Month % N=283	Total % Complication Incidence
Complications not requiring surgical intervention:							
Dura Related	3.1	-	-	-	0.2*	-	3.3
Neurologic	1.9	0.2	0.4	0.4*	-	-	2.9
Infection	-	2.1	0.2	-	0.1*	-	2.4
Implant Migration (no reoperation)	-	0.3	0.9	0.4	-	-	1.6
Ileus (post-op)	0.4	1.1	-	-	-	-	1.5
Vessel Damage, Bleeding	1.5	-	-	-	-	-	1.5
Atelectasis, Pneumonia	-	1.2	0.1	-	-	-	1.3
Hematoma, Seroma	0.1	1.0	0.1	0.1	-	-	1.3
Retorgrade Ejaculation	0.2	0.1	0.7	0.3	-	-	1.3
Other**	0.1	0.7	-	0.1	0.1	0.3	1.3
Urologic, Swollen Testicle, Prostatitis, Epididymitis	0.2	0.6	0.1	-	-	-	0.9
Wound Dehiscence, Incisional Hernia	-	0.4	0.1	0.1	0.1	-	0.7
Thrombophlebitis, Embolism	-	0.5	0.2	-	-	-	0.7
Leg Pain	0.1	0.1	0.1	-	-	0.3*	0.6
*Complications requiring surgical intervention:****							
Additional Stabilization	-	0.2	0.3	0.6	1.5	2.1	4.7
Additional Level Fusion	-	-	0.1	0.1	0.8	0.7	1.7
Implant Migration with Reoperation	-	0.6	0.5	0.1	-	-	1.2
Leg Pain with Decompression	-	0.4	0.1	0.1	0.3	0.3	1.2
Dura Related Comp with Repair	0.5	-	0.1	-	-	-	0.6
Reposition of Implants	-	0.3	-	0.1	-	-	0.4
Other Decompression	-	0.1	-	0.1	-	-	0.2
Penetration of Anterior Ligament	0.1	-	-	-	-	-	0.1
Fractured Sacrum with Instability	-	0.1	-	-	-	-	0.1

* Due to Secondary Surgical Intervention

** Other = anemia, colitis, GI bleed, wound drainage without infection, undisplaced sacral fracture, unrelated SI joint infection, chronic subdural hematoma, umbilical hernia (unrelated to surgery), loose implant perioperatively, occipital infarction, possible pre-existing disc space infection

*** Complications requiring surgical intervention include 9 revisions, 7 removals, 27 reoperations and 26 supplemental fixations.

Clinical Results

The following are clinical results of the same multi-center clinical study presented above. Two year data was available for 283 patients. The data are stratified by surgical approach and one versus two levels. The success rates are shown below for each criteria as well as overall success based on all four criteria.

The success rates are shown below for overall success as well as for each of the four criteria. Overall success was defined as fusion at the involved level(s), improvement in pain, maintenance or improvement in function and maintenance or improvement in muscle strength. Note that the number of patients with available data differ slightly due to unavailable data.

	Anterior One Level	Two Level
Overall Success	**81% (85/105)**	**59% (39/66)**
Fusion Rate	98% (106/108)	80% (56/70)
Pain Improvement	84% (93/111)	86% (62/72)
Function Maintenance or Improvement	95% (105/111)	94% (68/72)
Strength Maintenance or Improvement	94% (102/109)	94% (64/68)

	Posterior One Level	Two Level
Overall Success	**78% (52/67)**	**50% (8/16)**
Fusion Rate	94% (68/72)	71% (12/17)
Pain Improvement	87% (66/76)	81% (17/21)
Function Maintenance or Improvement	92% (70/76)	95% (20/21)
Strength Maintenance or Improvement	94% (67/71)	100% (20/20)

From the clincal data, the following statistical differences were observed among the subgroups up to or at the two year time period:

- The two year postoperative data indicates that the likelihood of needing additional supplemental fixation increases over time in patients who were not fused or showed no improvement in pain.
- For both the anterior and posterior approaches, patients with one level fusion had lower overall complication rates than patients with two level fusions.
- Patients implanted with the BAK device from the posterior approach had higher rates of intraoperative complications and early postoperative surgical interventions than patients implanted from the anterior approach.
- Patients implanted from the anterior approach had a higher overall rate of early postoperative complications than patients implanted
- For both the anterior and posterior approaches, patients who had higher preoperative baseline pain scores showed better pain improvement throughout the study than patients with lower baseline pain scores.

Device Retrieval Efforts

Should it be necessary to remove a BAK, please call Spine-Tech's Regulatory Affairs Department at 800/655-2614 for instructions regarding implant preparation, shipment and data collection.

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7375 Bush Lake Road
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FAX 832-5620

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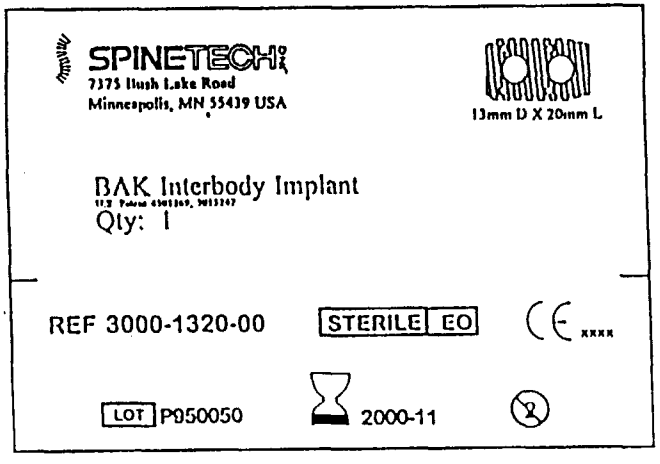

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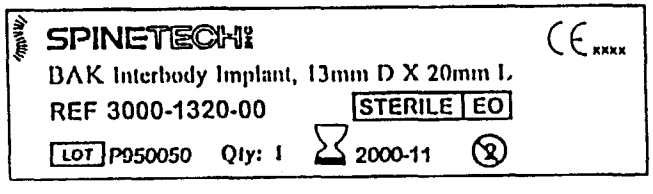

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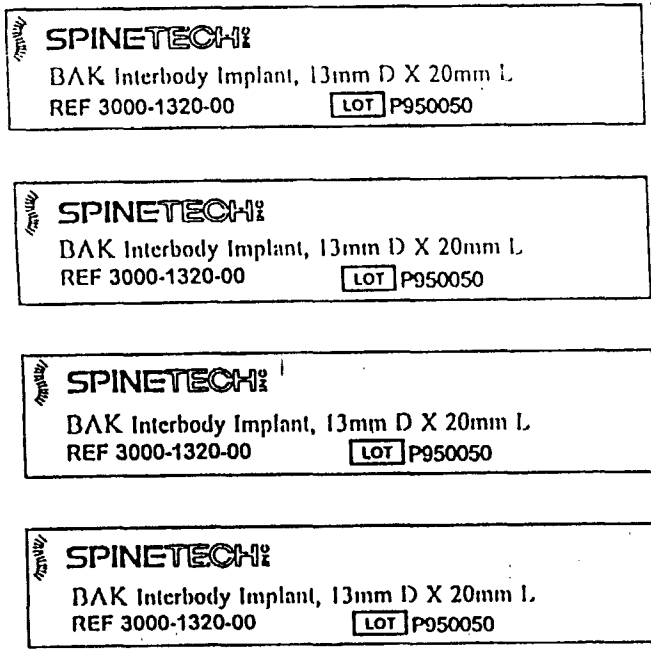

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Minneapolis, MN 55439 USA

13mm

BAK™ Endcap, 13mm
U.S. Patent [illegible]
Qty: 1

REF 3000-13PE-00 STERILE EO CE 0044

LOT

BAK™ ENDCAP SIZE: 13mm

OUTER TYVEK POUCH LABEL

SPINETECH CE xxxx
BAK™ Endcap, 13mm
REF 3000-13PE-00 STERILE EO
LOT Qty: 1

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BAK™ Endcap, 13mm
REF 3000-13PE-00 LOT

SPINETECH
BAK™ Endcap, 13mm
REF 3000-13PE-00 LOT

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BAK™ Endcap, 13mm
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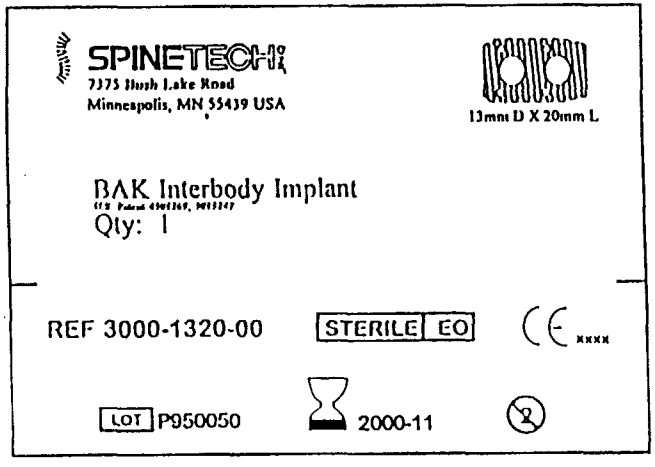

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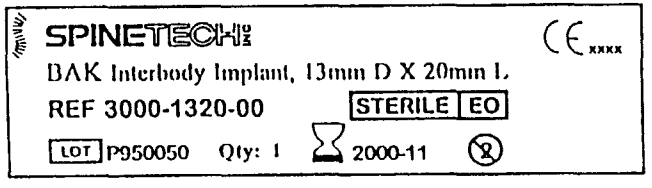

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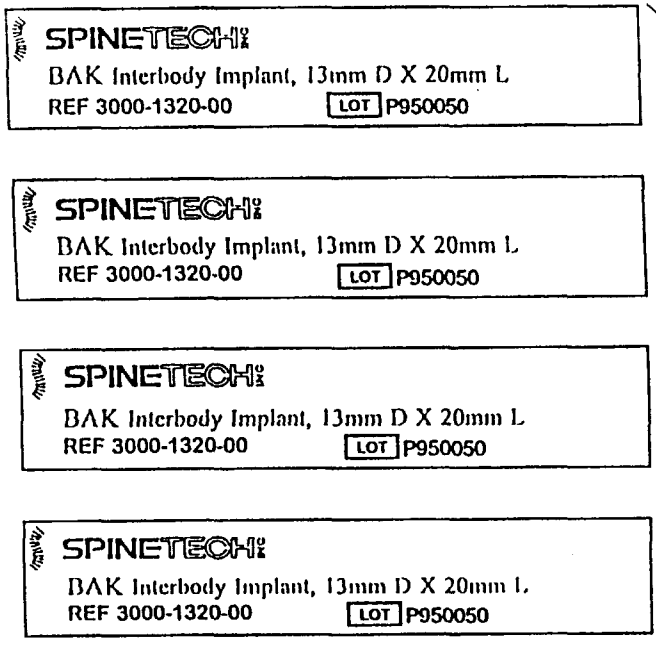

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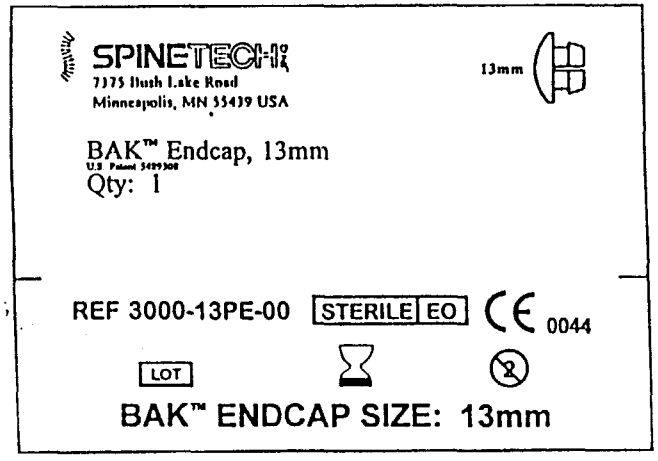

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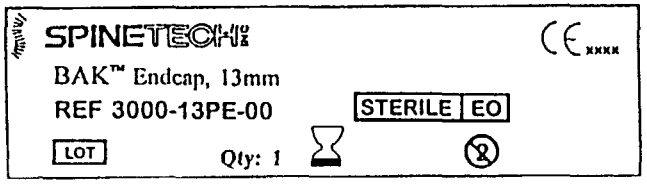

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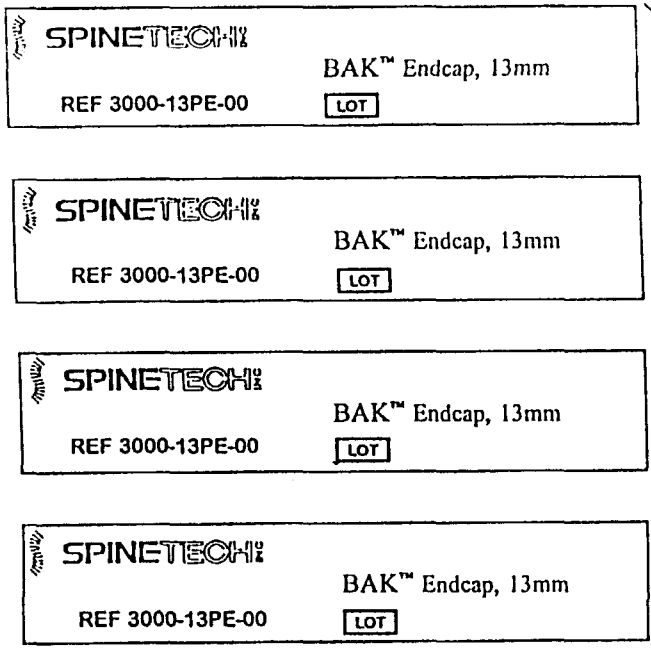

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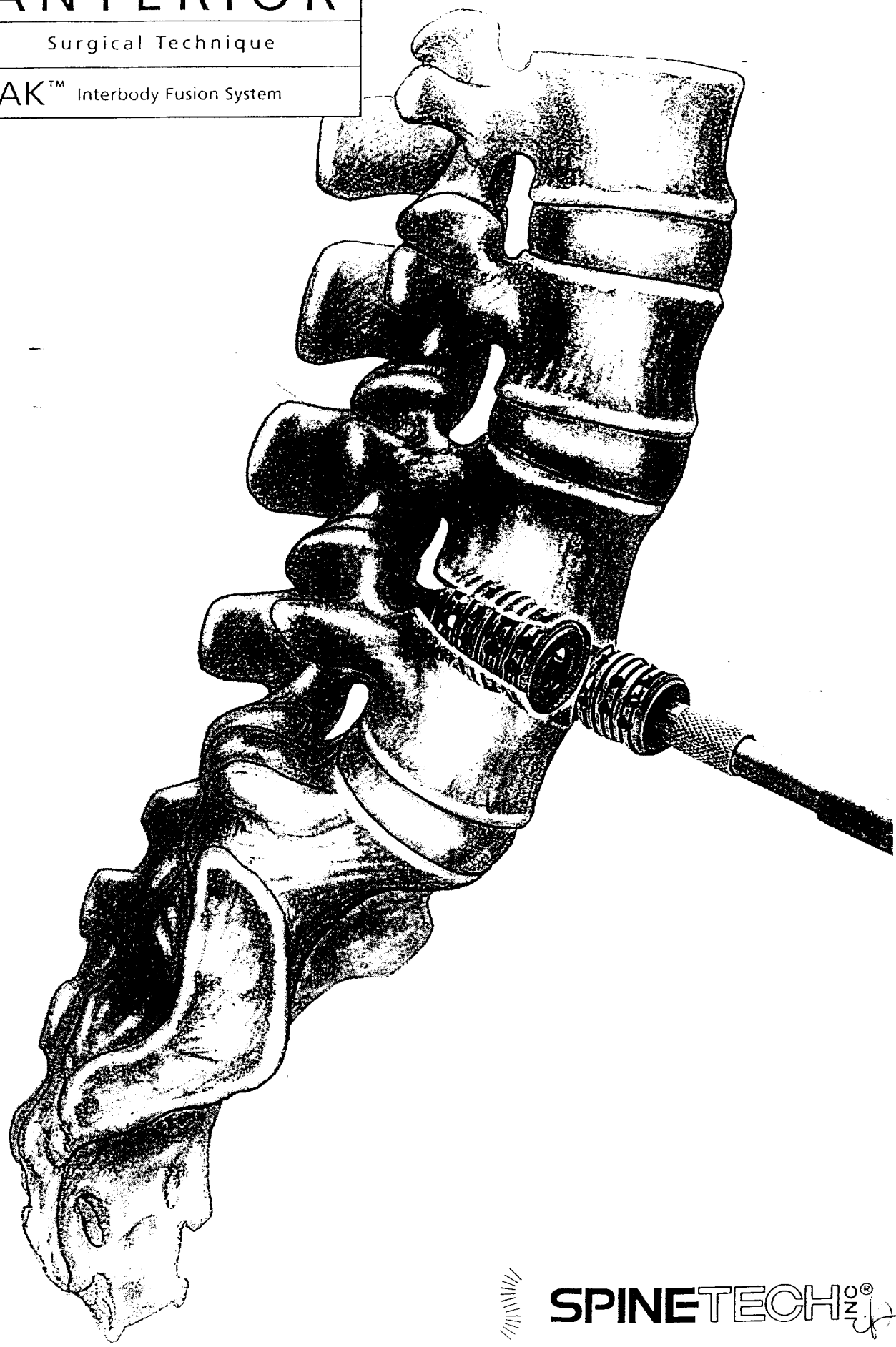
ANTERIOR

Surgical Technique

BAK™ Interbody Fusion System



SPINETECH INC®

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Anterior Surgical Technique

The Spine-Tech BAK implant is a fenestrated, threaded, cylindrical, titanium alloy device to be inserted within the intervertebral disc space. The implant is coupled with instruments designed to reproducibly prepare the bone bed, protect surrounding tissues and safely position the implants. The system is designed to provide an immediately stable motion segment to allow fusion and relief of symptoms.

Design features of the BAK implant include:

- Vertebral distraction evenly tenses the remaining annulus creating a tension band around the implants
- Threads engage the vertebral body to enhance resistance to shear forces
- "Keystone" effect resists rotational forces
- Internal ribbing to enhance fatigue strength
- Lordosis maintained through vertebral body support
- Foraminal volume and area are increased through distraction providing decompression

Design features of the BAK instruments include:

- Drill tubes aid in retraction and protection of vital structures during implantation
- Positive stops prevent overdrilling
- Drill Tube teeth ease tube docking and prevent instrument migration
- Alignment Guides facilitate accurate implant insertion and spacing

Indications, contraindications, potential adverse effects and precautions are referenced in the package insert.

Radiographic templating assists with selecting appropriate implant and Distraction Plug sizes which maximize implant endplate coverage and create proper vertebral distraction and annular tension. Selection of the proper size BAK implants is critical for optimum results.

Radiographic templates (Figure 1) are available in 15% magnification for use with plain x-rays and 50% to 80% reductions for MRI and CT scans. Templates include the following information:

- Implant size and distraction plug size chart
- Lateral BAK implant and associated drilling representations
- Lateral distraction plug representations
- Anterior/Posterior implant representations
- Magnification or reduction scale

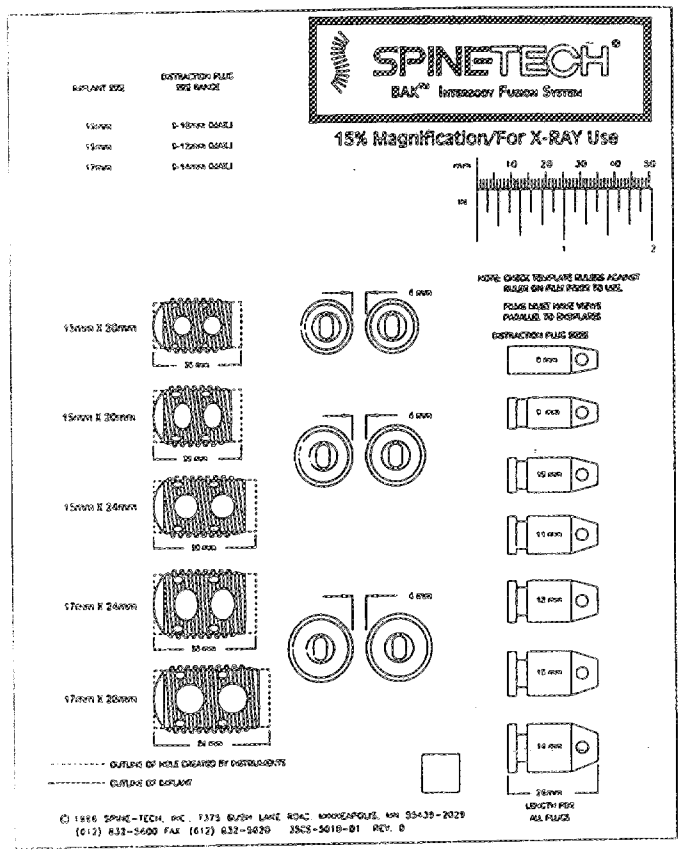

Figure 1

Step 1

The proper implant length is assessed with a lateral x-ray. The red dotted lines, representing the final reaming depths, and lateral implant representations are overlaid on the affected disc (Figure 2). Select the maximum reaming depth and implant size which is safely contained within the anterior and posterior vertebral margins.

This assessment will typically reduce the implant selections to one length and two diameters.

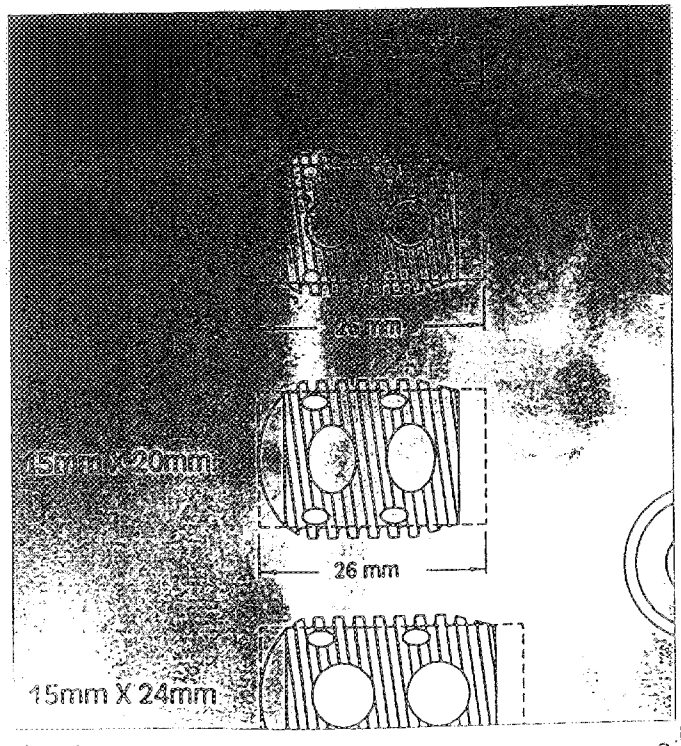

Figure 2

Step 2

On the same lateral x-ray, overlay the Distraction Plug outline on an adjacent healthy disc (Figure 3). The Distraction Plug which bridges the space is an indication of the potential distraction of the affected motion segment.

Step 3

Compare the implant diameters indicated in Step 1 with the Distraction Plug size indicated in Step 2 using the Implant Size/Distraction Plug Size Range chart in the upper left hand corner of the template.

If the Distraction Plug size indicated in Step 2 is not within the range listed for the smaller implant diameter, the larger implant diameter is selected. If it is, the A/P x-ray is used to further assess the correct implant size.

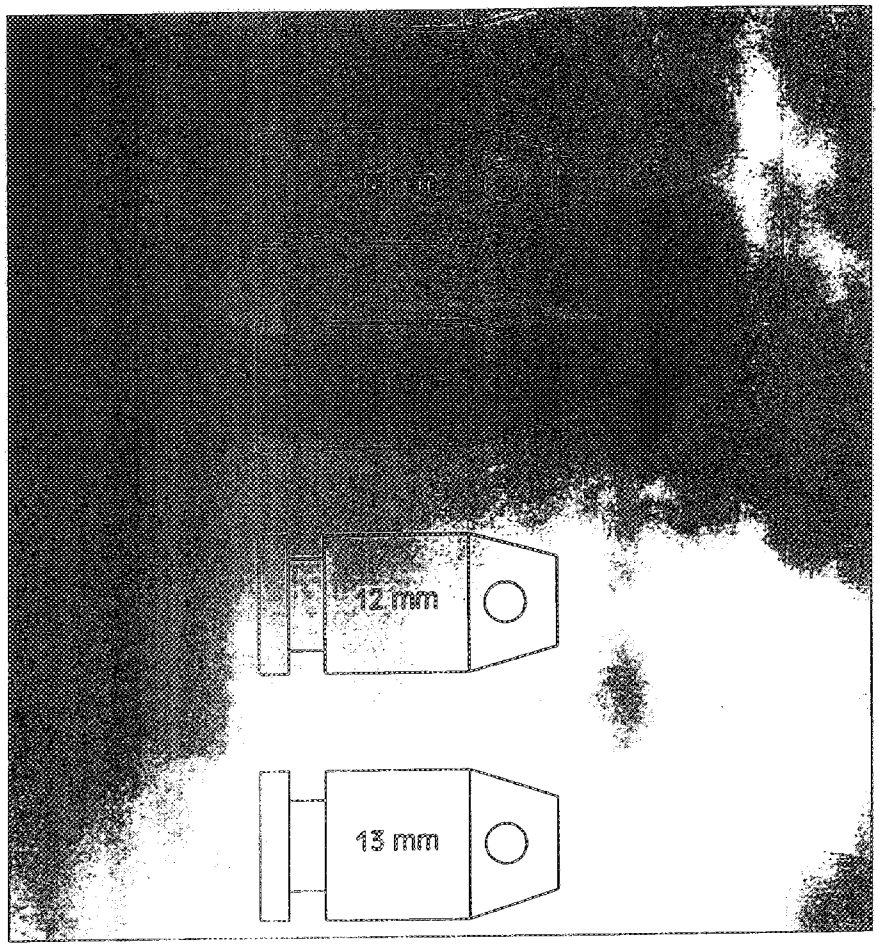

Figure 3

The Implant Size/Distraction Plug Size Range chart is recreated below.

Implant Size	Distraction Plug Size Range
Size 13mm	9-10mm (max.)
Size 15mm	9-12mm (max.)
Size 17mm	9-14mm (max.)

Note: As a general rule, for the implant to obtain adequate purchase into the vertebral bodies, it must be at least 3mm larger than the Distraction Plug used.

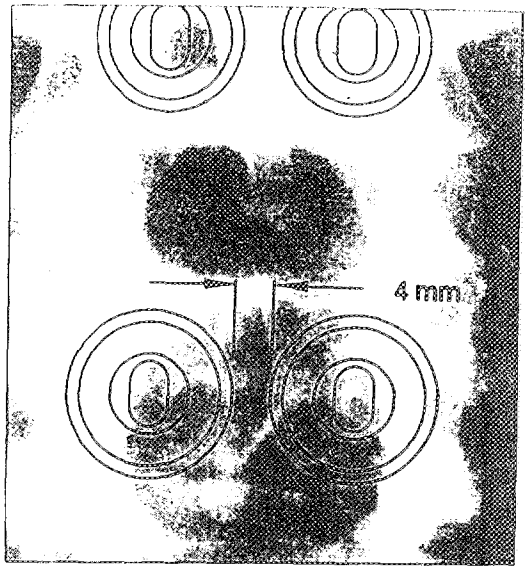

Figure 4

Step 4

The appropriate implant diameter is further assessed or confirmed by overlaying the A/P BAK outlines of the implant diameters determined in Steps 1 and 2, over the A/P x-ray. Center the images over the superior most vertebral body to be fused (Figure 4). The largest implant representations which fit within the lateral margins indicate the implant size to be used.

An MRI/CT axial cut reflecting the smallest endplate of the affected disc can help determine implant size. To select the proper BAK MRI/CT template, match the scale on the template to that of the scan (Figure 5). Use the bilateral axial template images to assess the largest outlines which are safely contained within the disc margins (Figure 6).

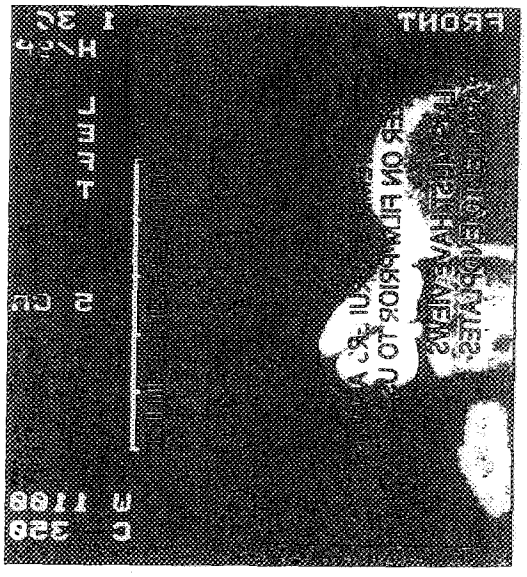

Figure 5

Caution: When using the MRI/CT templates, it is critical that the transverse vertebral representations are parallel to the endplates. If they are not, the images will be oversized and may lead to selection of an implant and associated drilling depth which is too long.

Note: Templating provides an estimate of implant and distraction plug size. Final sizes will be determined intraoperatively.

After implant size selection is complete, the common instruments and the instruments specific to the selected implant size are removed from the instrument trays.

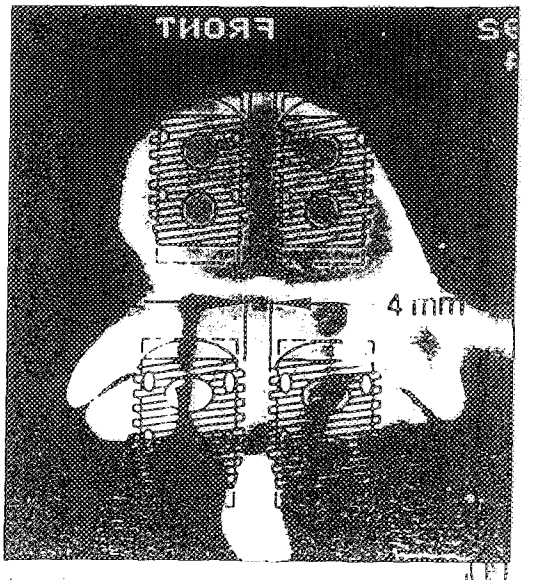

Figure 6

The patient is placed in the supine position and general anesthesia is administered. A pad is placed under the lumbar spine to maintain lordosis (Figure 7) and the arms are positioned 90 degrees to the torso on boards to better facilitate radiographic imaging (Figure 8). A vascular or general surgeon usually provides the exposure while the spine surgeon assists and then performs the implantation. The lumbar spine is exposed through a low transverse or paramedian incision, and a retroperitoneal plane is developed.

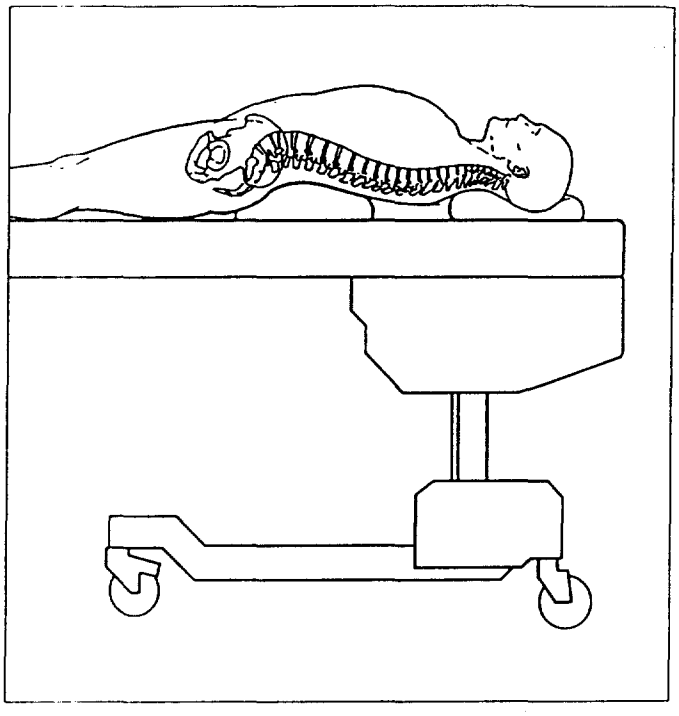

Figure 7

The anterior rectus sheath is split longitudinally about 3 to 4cm left of the midline anterior to the level(s) to be fused. Since the BAK implantation will be accomplished in a direct anterior-posterior plane, the retroperitoneal plane must be developed from an anterior rather than lateral direction. This is most easily accomplished by retracting the left rectus abdominus muscle laterally to the left. In addition to providing a more direct anterior to posterior plane, the retraction tension on the left rectus is reduced and the blood flow to the muscle is improved. This exposes the peritoneum below the arcuate line and the posterior rectus sheath above it. The peritonium is stripped from the undersurface of the posterior rectus sheath, and the rectus sheath is divided near its insertion on the lateral wall, from inferior to superior, until sufficient exposure is achieved. The left psoas, great vessels, left ureter, and left sympathetic trunk are identified and protected from injury.

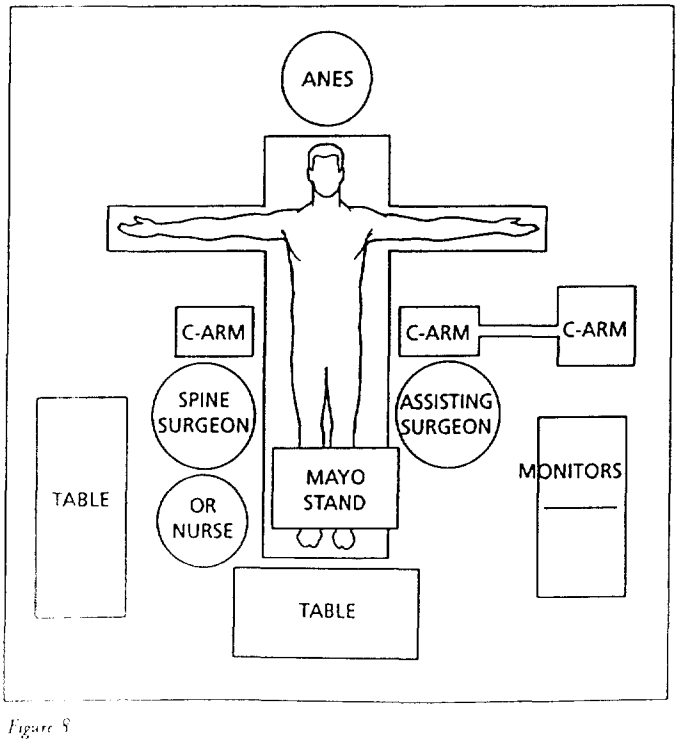

Figure 8

Caution: *Electro-cautery of any kind must be used very* sparingly, if at all, in the tissues around and between the great vessels and the anterior surface of the spine in order to minimize risk of injury to the autonomic nerve plexus. This plexus is thought to be involved with the complication of retrograde ejaculation.

Normally, the L5-S1 disc level can be exposed below the bifurcation of the great vessels (Figure 9), while the exposure of the L4-5 level and above requires the left iliac vein and/or vena cava be mobilized to the right lateral margin of the spine (Figure 10). The middle sacral vessels, segmental vessels above the disc to be fused and the ascending lumbar vein may need to be identified, ligated and sectioned to provide adequate exposure without excessive traction on the great vessels. The Buckwalter Frame and Wiley Renal Vein Retractors greatly facilitate the operation.

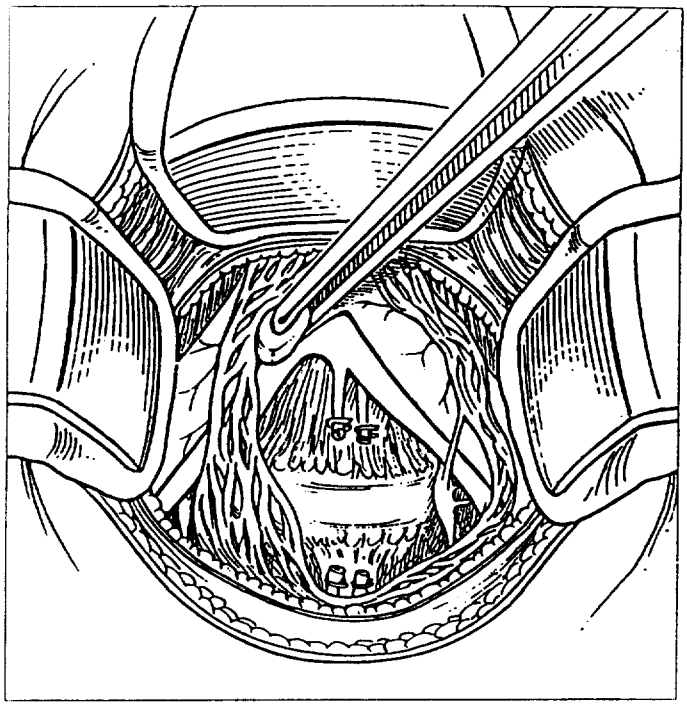

Figure 9

Following complete exposure of the anterior aspect of the spine, a pin or needle is inserted approximately in the midline. An anterior-posterior radiograph is taken to verify the location of the midline. Identification and radiographic confirmation of this landmark is critical to ensure accurate bilateral implant placement.

If iliac crest graft is to be used within the implants, sufficient bone graft can be harvested from the anterior iliac crest in cases of one level-fusion. However, a preliminary posterior iliac graft harvest may be necessary for two-level fusions. About five to seven cubic centimeters of compacted cancellous graft is necessary for each implant.

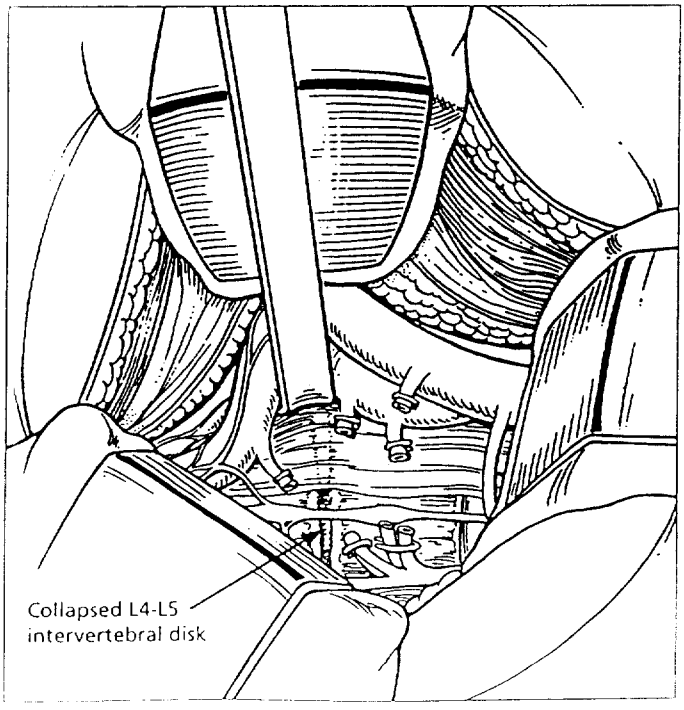

Figure 10

NECESSARY INSTRUMENTS

Anterior Alignment Guide
8mm Drill

The Anterior Alignment Guide is used to establish the proper position of two BAK implants parallel within the intervertebral space and to initiate the discectomy procedure. It is designed to place the implants 4mm apart.

Cut a small vertical slit in the previously established midline of the involved disc with a size 15 scalpel blade. Insert the guide peg of the Anterior Alignment Guide into the slit (Figure 11). Using a mallet, secure the spikes into the vertebral bodies with the guide holes centered over the disc. Slit the annulus visible through the lower guide hole with the scalpel blade. Insert the 8mm Drill through the Alignment Guide and drill until the positive stop on the drill contacts the top of the Alignment Guide (Figure 12).

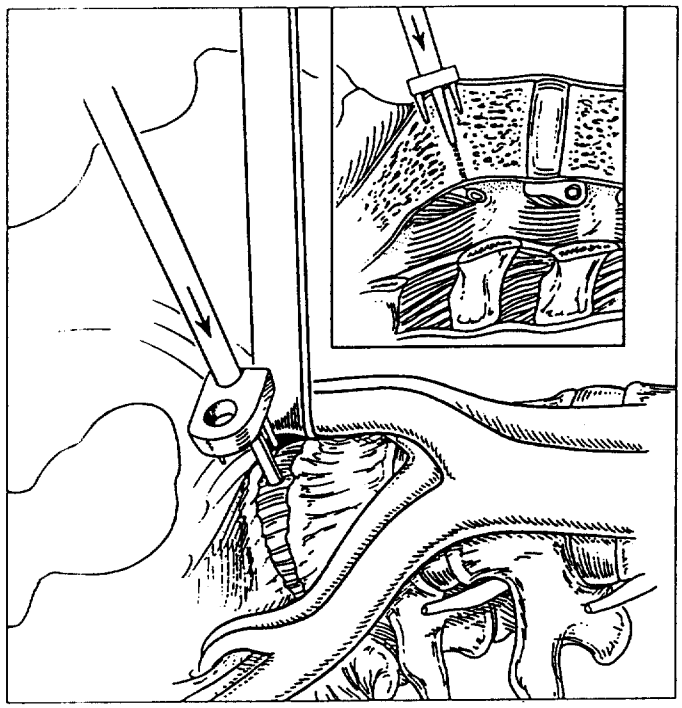

Figure 11

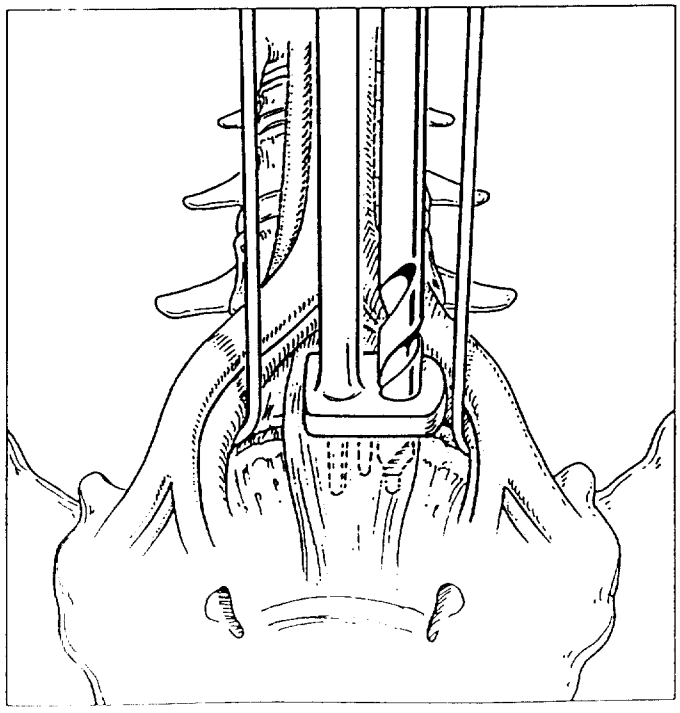

Figure 12

Disengage the spikes and rotate the Alignment Guide in the central hole 180°. Resecure the Alignment Guide and prepare the disc space for the second implant using the 8mm Drill as described previously.

Note: Using a pituitary rongeur and/or small curette, nucleus material can be removed through the drill holes (Figure 13). Additional annulus may also be removed, but care should be taken to remove an equal amount around the original 8mm holes. Avoid elongation of the holes and decortication of the endplate as it may affect Distraction Plug or Guide Pin placement and subsequent alignment.

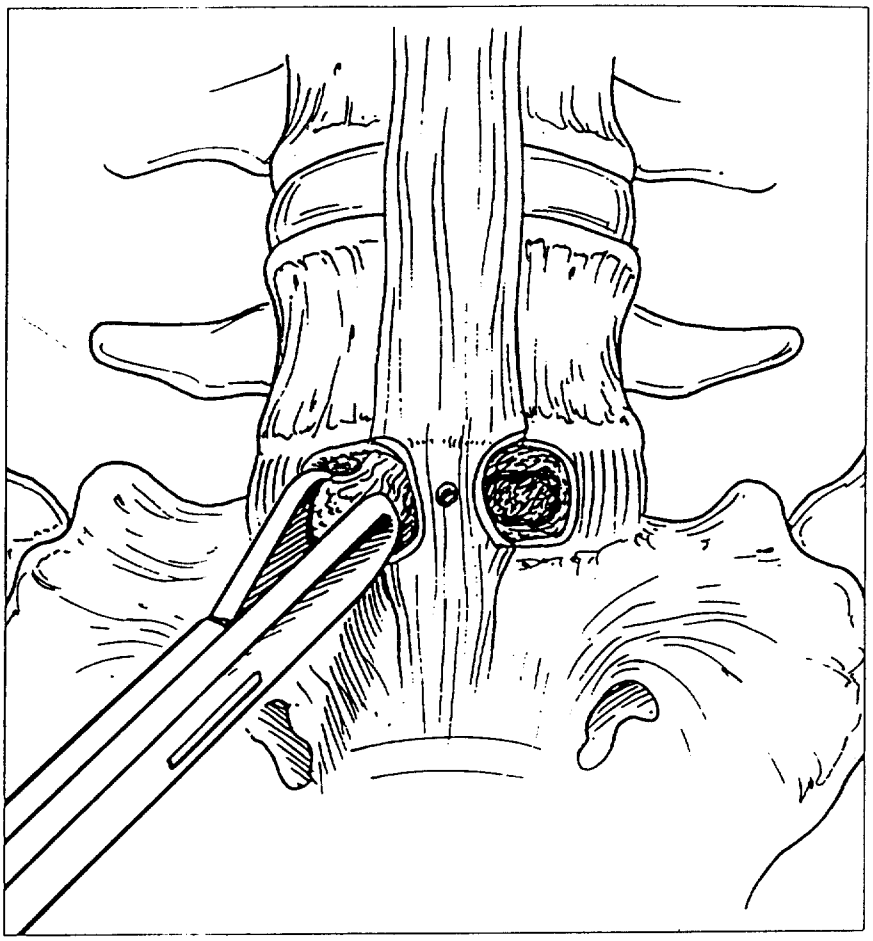

Figure 13

NECESSARY INSTRUMENTS

Distraction Plug Inserter
Distraction Plugs

Distraction Plugs are used to distract the vertebral bodies and apply tension to the annulus prior to vertebral reaming.

Attach a relatively small Distraction Plug onto the Distraction Plug Inserter. Retract the vessels with a vein retractor and impact the Distraction Plug into one of the 8mm drill holes (Figure 14). The Distraction Plug is impacted until the back edge of the plug is slightly recessed below the anterior margin of the disc. Check the annular tension by pulling straight up on the Distraction Plug Inserter. If the Distraction Plug pulls out easily, repeat this procedure using incrementally larger Distraction Plugs until the annulus is sufficiently taut. This is indicated when significant resistance is met during Distraction Plug removal.

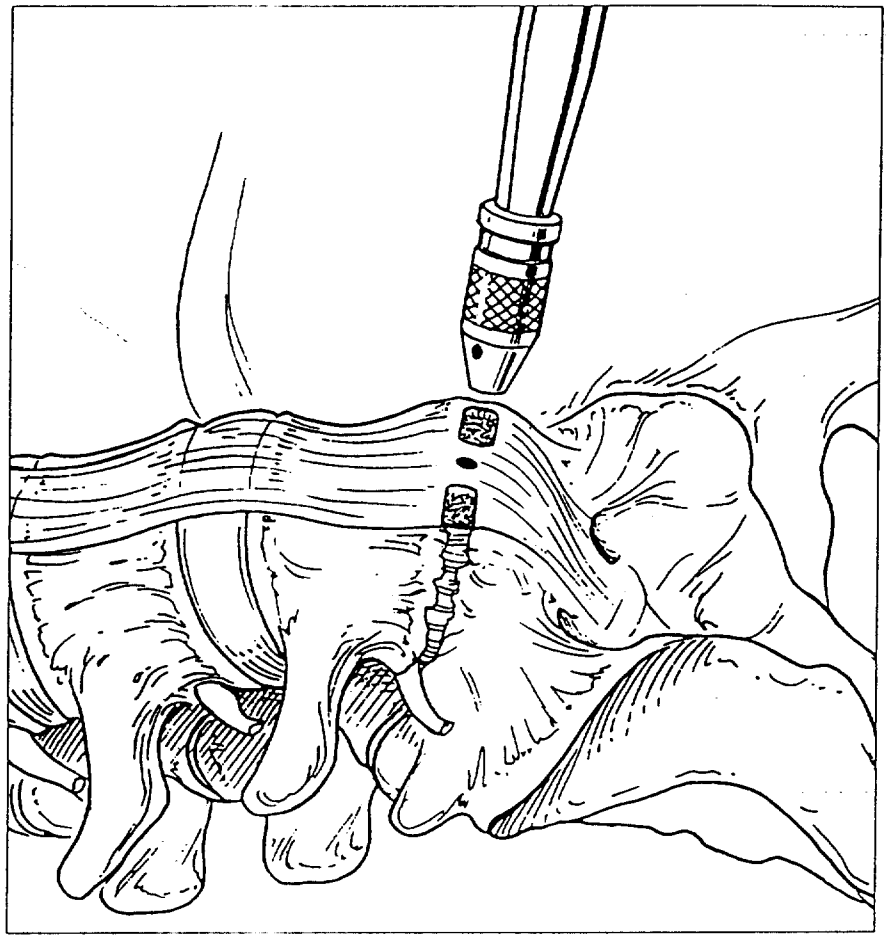

Figure 14

Once the correct Distraction Plug is identified, assess the disc space angle by noting the angle of the Distraction Plug Handle (Figure 15). This angle is critical as all future drilling, tapping and implantation steps need to be performed at this angle. Remove the handle, leaving the Distraction Plug in place.

Note: As a general rule, for the implant to obtain adequate purchase into the vertebral bodies, it must be at **least** 3mm larger than the Distraction Plug used. See chart below.

Implant Size	Distraction Plug Size Range
Size 13mm	9-10mm (max.)
Size 15mm	9-12mm (max.)
Size 17mm	9-14mm (max.)

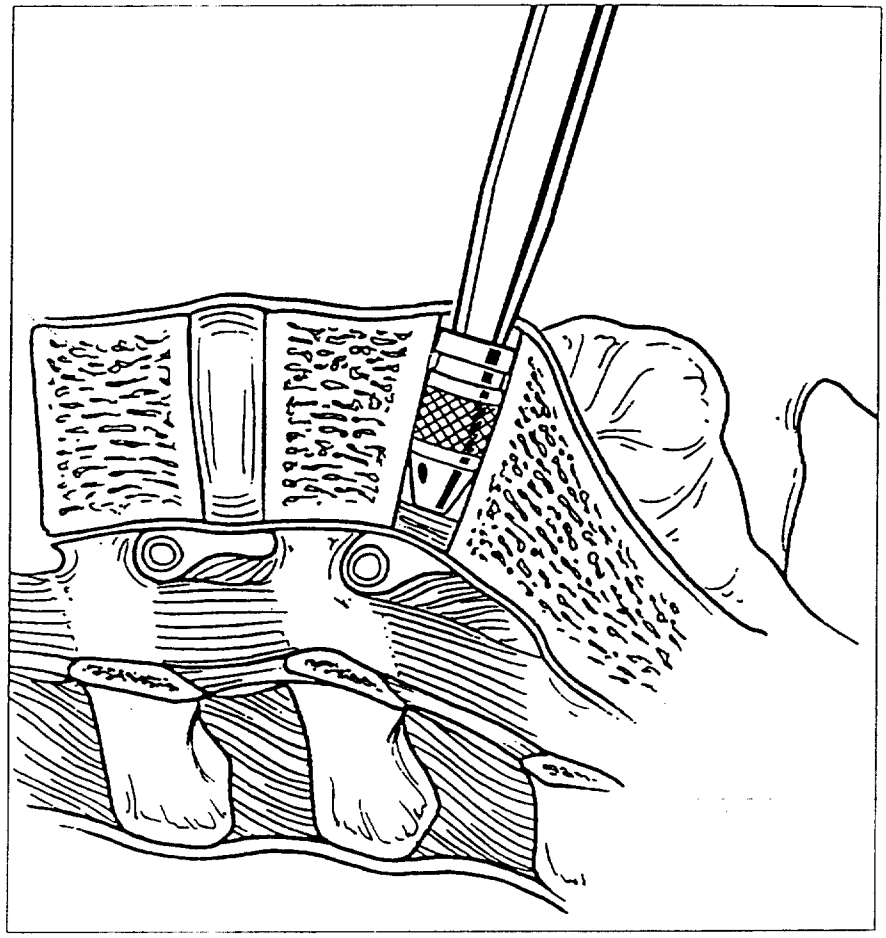

Figure 15

NECESSARY INSTRUMENTS

Drill Tube Guide	Drill Tube
Guide Pin	Drill Tube Sheath
Slap Hammer	Alignment Guide Handle

Thread a Guide Pin equivalent in size to the inserted Distraction Plug onto the Drill Tube Guide.

Impact the Drill Tube Guide and Guide Pin into the 8mm drill hole opposite the Distraction Plug (Figure 16). This will center the Drill Tube Guide over the disc.

Slide the protective Drill Tube Sheath onto the Drill Tube with the curved end of the Drill Tube Sheath placed distally and covering the anchoring teeth (Figure 17). Slide the Drill Tube and Sheath over the Drill Tube Guide.

Caution: Prior to anchoring the Drill Tube, great care must be taken to identify and retract all soft tissue.

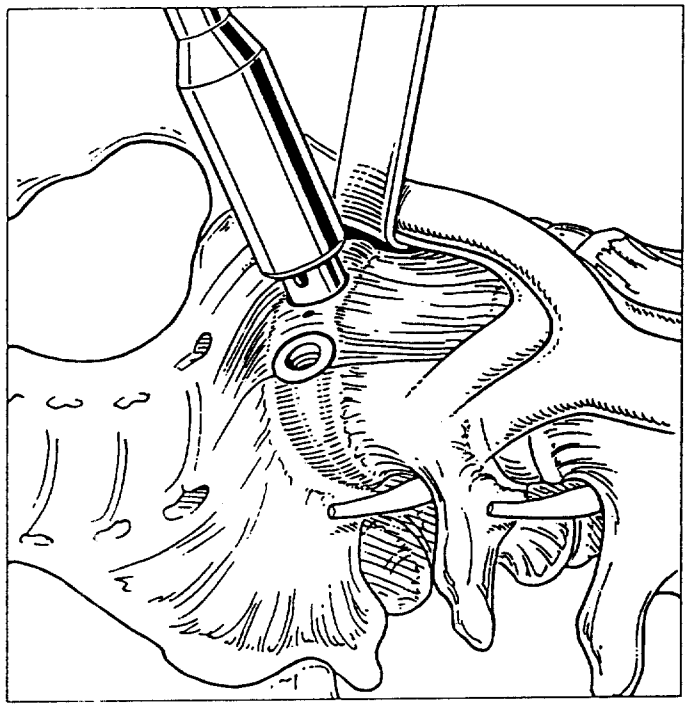

Figure 16

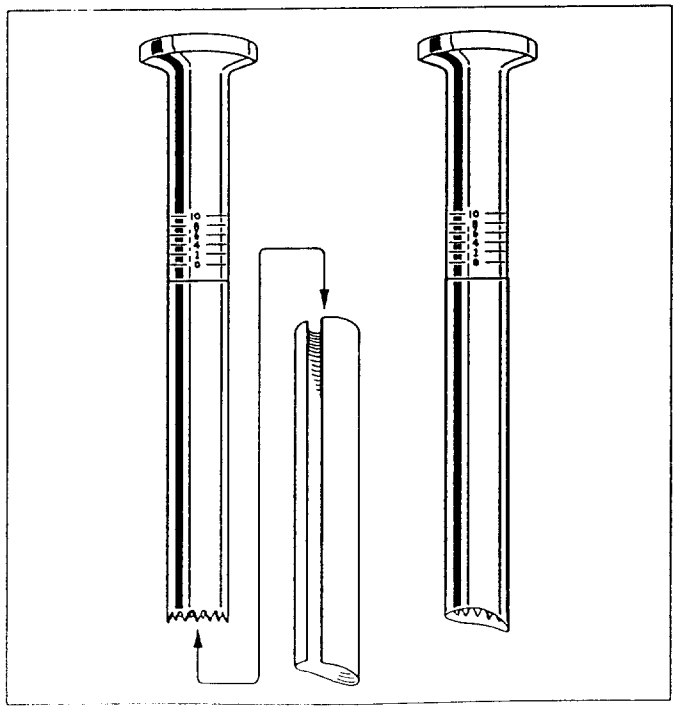

Figure 17

Using lateral radiographic imaging, ensure the superior and inferior sides of the Drill Tube are aligned parallel to the vertebral endplates. Additionally, visually inspect and ensure the Drill Tube is perpendicular to the coronal plane of the disc. If a convergent angle is placed on the Drill Tube, it may cause the implants to contact one another. Conversely, a divergent angle may cause the implants to break out of the disc laterally, disrupting the annular tension band.

Place the Slap Hammer over the Drill Tube Guide and Drill Tube. Secure the anchoring teeth of the Drill Tube into the vertebral bodies by impacting the Slap Hammer until the inner surface of the Drill Tube Guide and Slap Hammer meet (Figure 18).

Once the Drill Tube is secure and alignment is verified, remove the Drill Tube Guide and Guide Pin by rotating the Drill Tube Guide clockwise and pulling straight up while applying downward pressure to the Drill Tube.

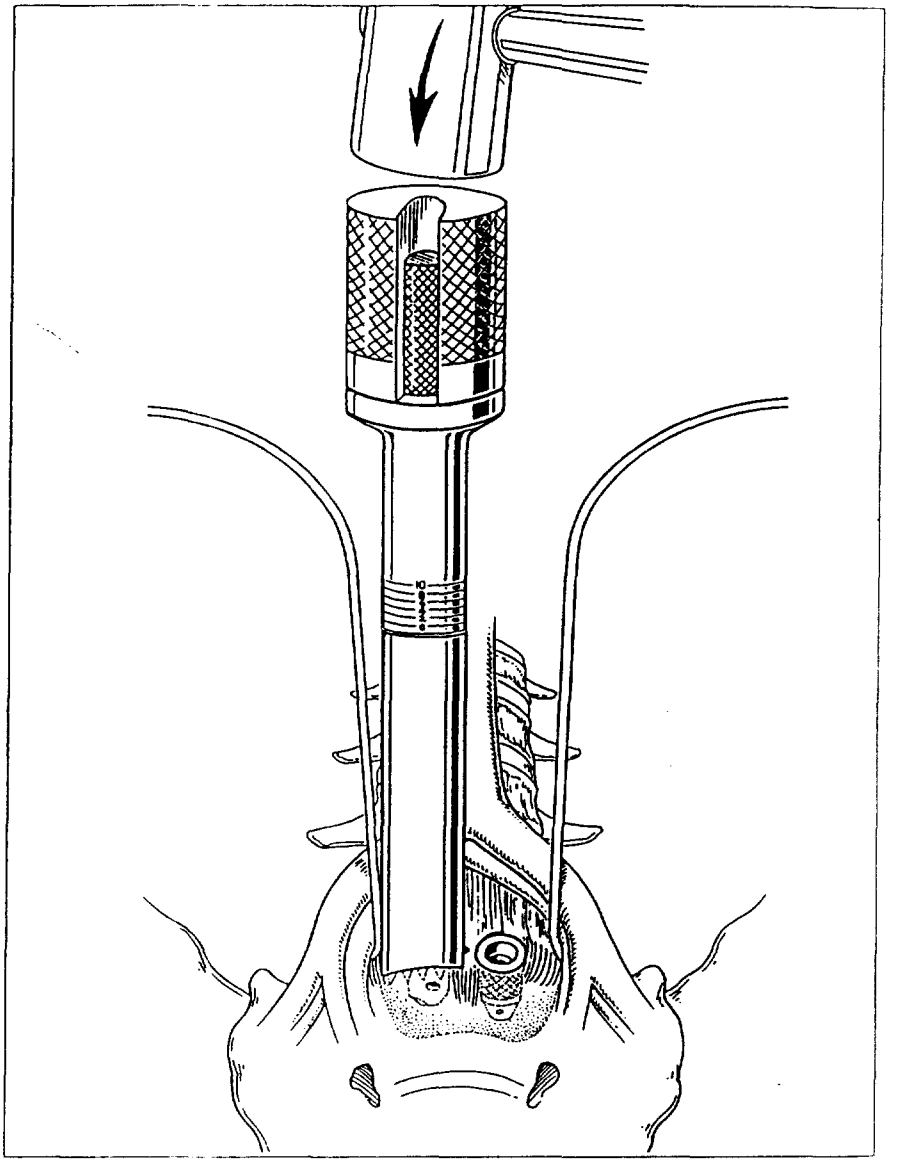

Figure 18

If extreme difficulty is experienced while removing the Drill Tube Guide and Guide Pin, screw the Alignment Guide Handle into the top of the Drill Tube Guide and use the Slap Hammer to vertically impact the bottom of the knob on the Alignment Guide Handle while applying downward pressure to the Drill Tube.

NECESSARY INSTRUMENTS

Short Series Spacer

If size 15 x 20 or 17 x 24 BAK implants are to be used, it is necessary to reduce the drilling, tapping and implanting depths. This is accomplished by increasing the length of the Drill Tube.

Slide the Short Series Spacer onto the top of the Drill Tube prior to reaming (Figure 19). This spacer lengthens the Drill Tube and shortens the reaming, tapping and implantation depths by 4mm.

Implant	Reaming Depth
15 x 20	26mm
17 x 24	30mm

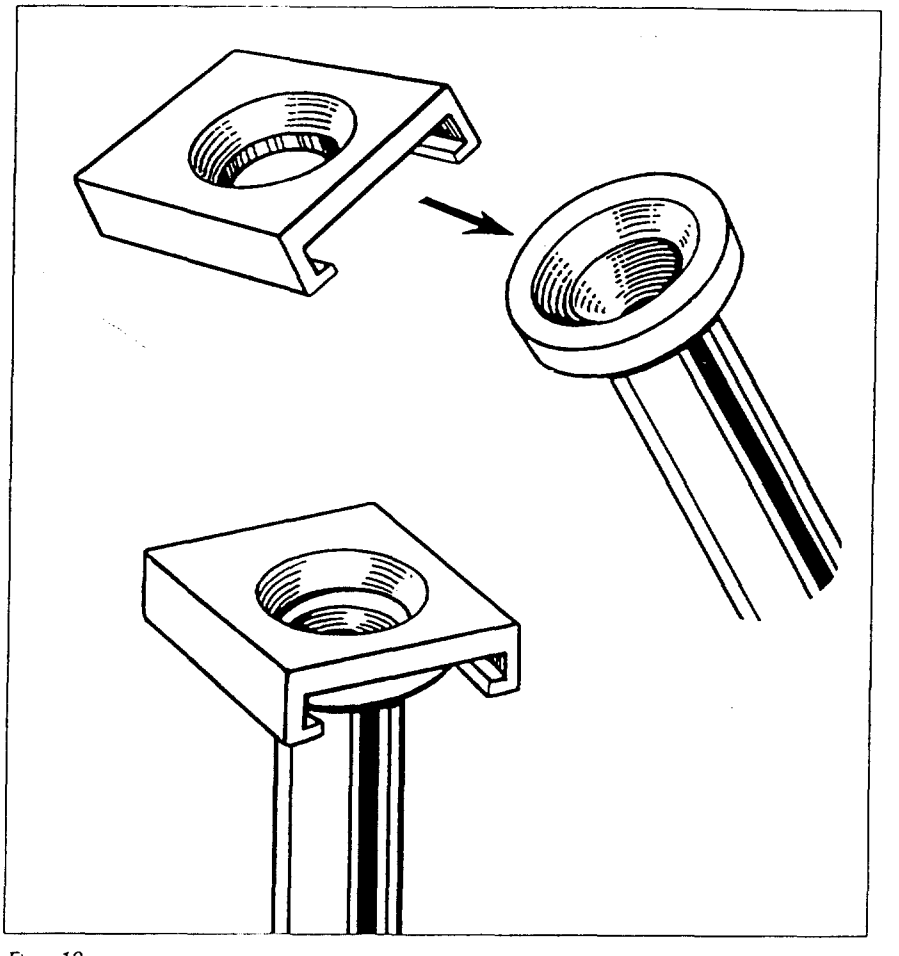

Figure 19

STEP 5 VERTEBRAL REAMING

Anterior Surgical Technique

NECESSARY INSTRUMENTS

T-Handle	Guide Pin
Starter Reamer	Pituitary Rongeur
Final Reamer	Drill Tube Sheath
Drill Tube Sleeve	

Slide the Drill Tube Sleeve into the Drill Tube (Figure 20).

Thread a Guide Pin the same size as the Distraction Plug onto the Starter Reamer.

While maintaining appropriate Drill Tube alignment and downward pressure, advance the Starter Reamer until the positive stop makes contact with the top of the Drill Tube (Figure 21). Remove the Starter Reamer while continuing to rotate it clockwise. This will prevent the Guide Pin from unthreading and ensure that debris is trapped within the reamer flutes.

Note: Lateral radiographic images may be taken during reaming to assess depth and endplate purchase.

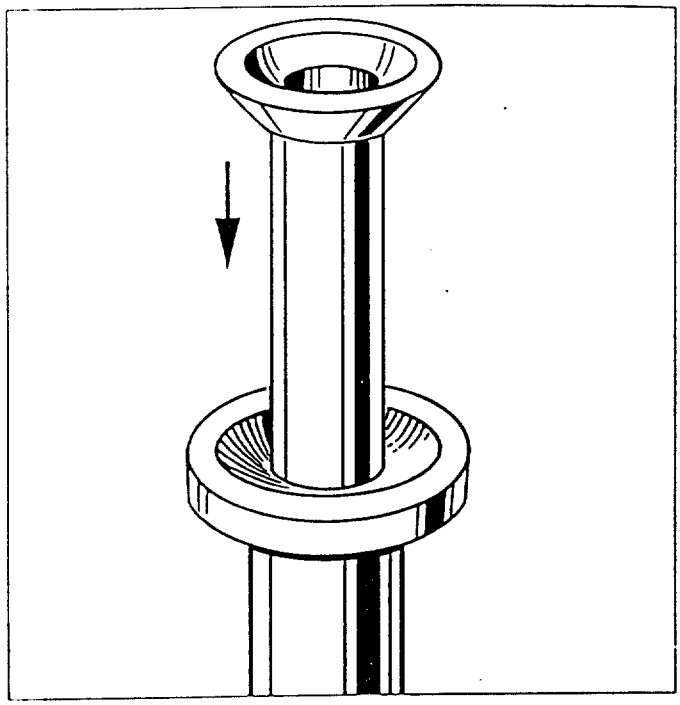

Figure 20

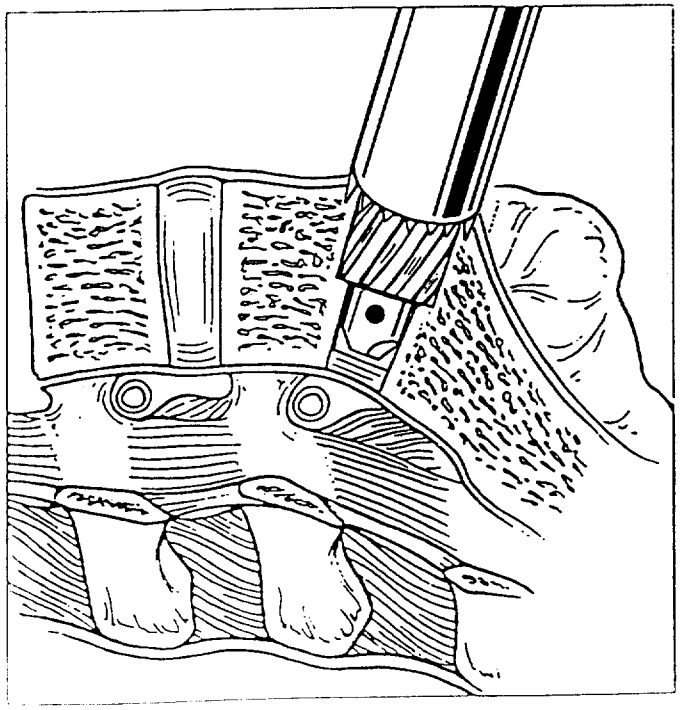

Figure 21

Insert the Final Reamer into the Drill Tube and advance until the positive stop makes contact with the top of the Drill Tube (Figure 22). Final reaming depth is noted radiographically and saved to aid in final placement of the implant. Reaming depth should show penetration into the posterior third of the disc space. Remove the Final Reamer while rotating it clockwise.

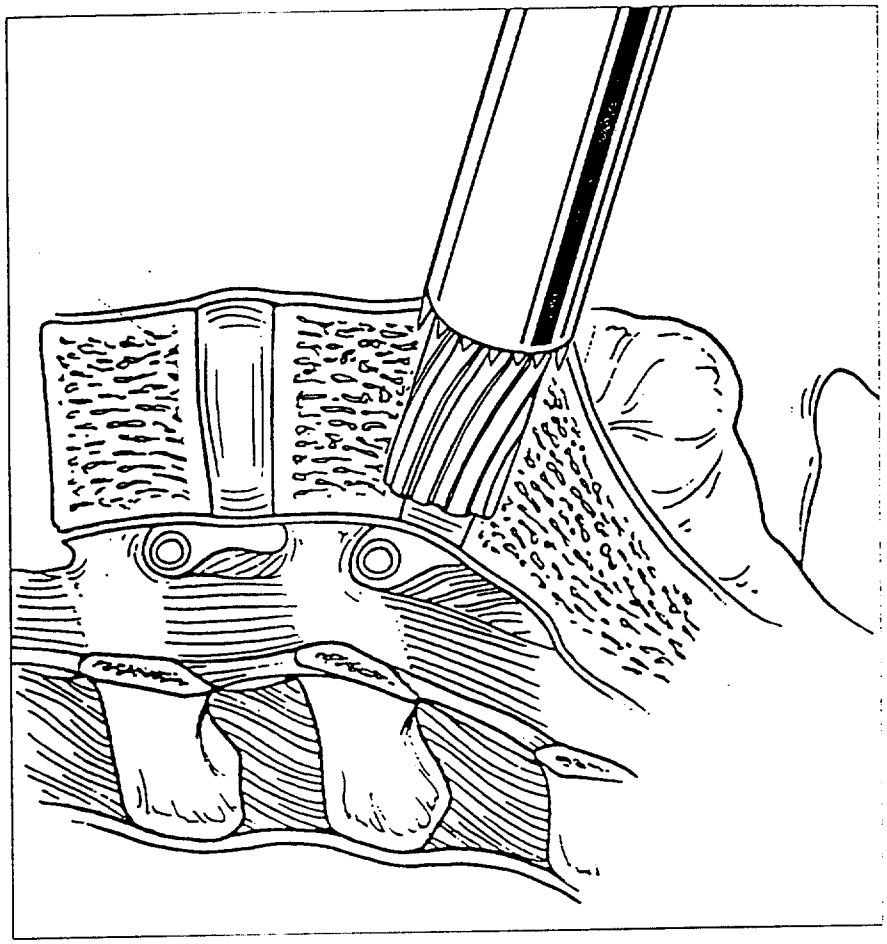

Figure 22

Note: If additional reaming depth is desired, it is necessary to advance the Drill Tube further. To control the additional depth of reaming, an impaction ruling is etched onto the Drill Tube. As the Drill Tube is impacted directly, it will move relative to the Drill Tube Sheath. By noting the ruling etched onto the Drill Tube, an indication of the millimeters advanced can be assessed. If this step is deemed necessary, additional depth should be achieved in multiple small incremental advances and caution should be exercised to prevent overreaming.

Remove the Drill Tube Sleeve.

To prevent disc material from retropulsing, remove any remaining disc material using the long Pituitary Rongeur. This can be accomplished by passing the Pituitary Rongeur through the Drill Tube and grasping the remaining fragments that may be at the bottom of the hole (Figure 23).

Caution: Care should be taken to ensure the posterior annulus is not penetrated with the Pituitary Rongeur. To control the depth of the Pituitary Rongeur, insertion etchings have been placed on the shaft of the instrument corresponding to the implant diameters. Prior to grasping material, note the locations of the etchings in relation to the top of the Drill Tube and palpate the bottom of the hole with the Pituitary Rongeur closed to ensure the annulus is intact.

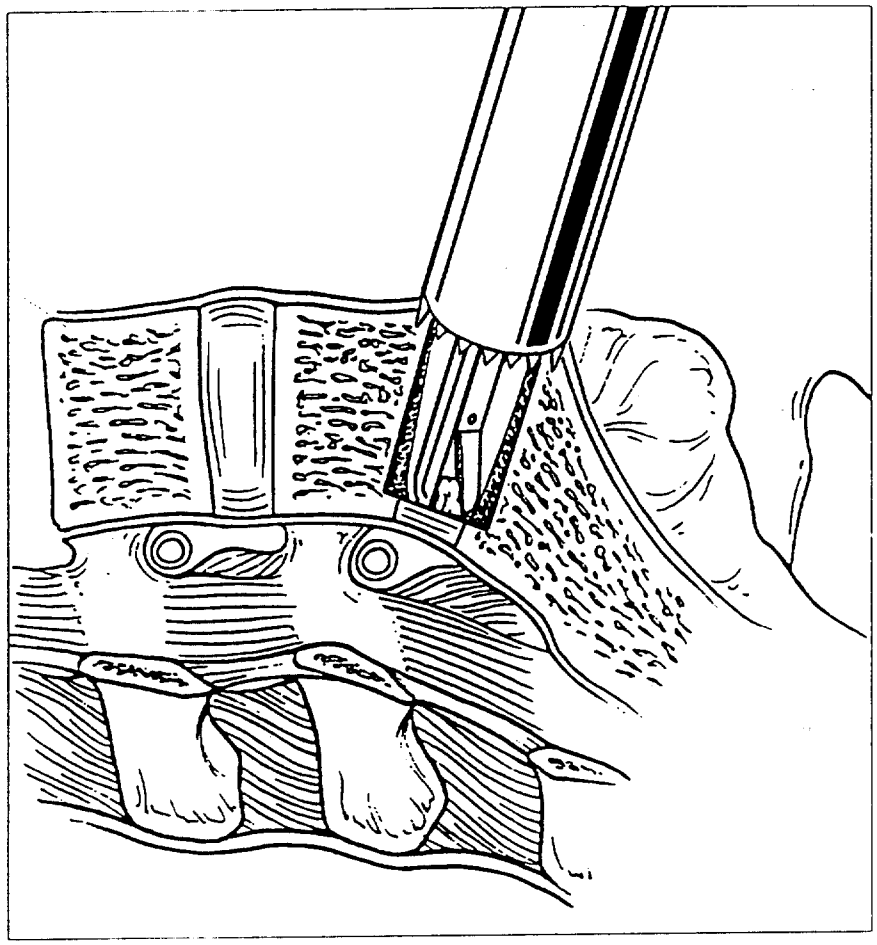

Figure 23

STEP 6 TRIAL IMPLANT PLACEMENT (OPTIONAL)

Anterior Surgical Technique

NECESSARY INSTRUMENTS

Trial Implant
Distraction Plug Inserter

Trial Implants are available to assess final drilling depth and implant location.

Thread the appropriate Trial Implant onto the Distraction Plug Inserter. Insert the Trial Implant through the Drill Tube and into the prepared hole (Figure 24). A lateral radiographic image is taken to verify reaming depth and implant position. The Trial Implant should be recessed 3-4mm below the anterior margin of the vertebral bodies and show placement into the posterior third of the disc space.

Remove the Trial Implant.

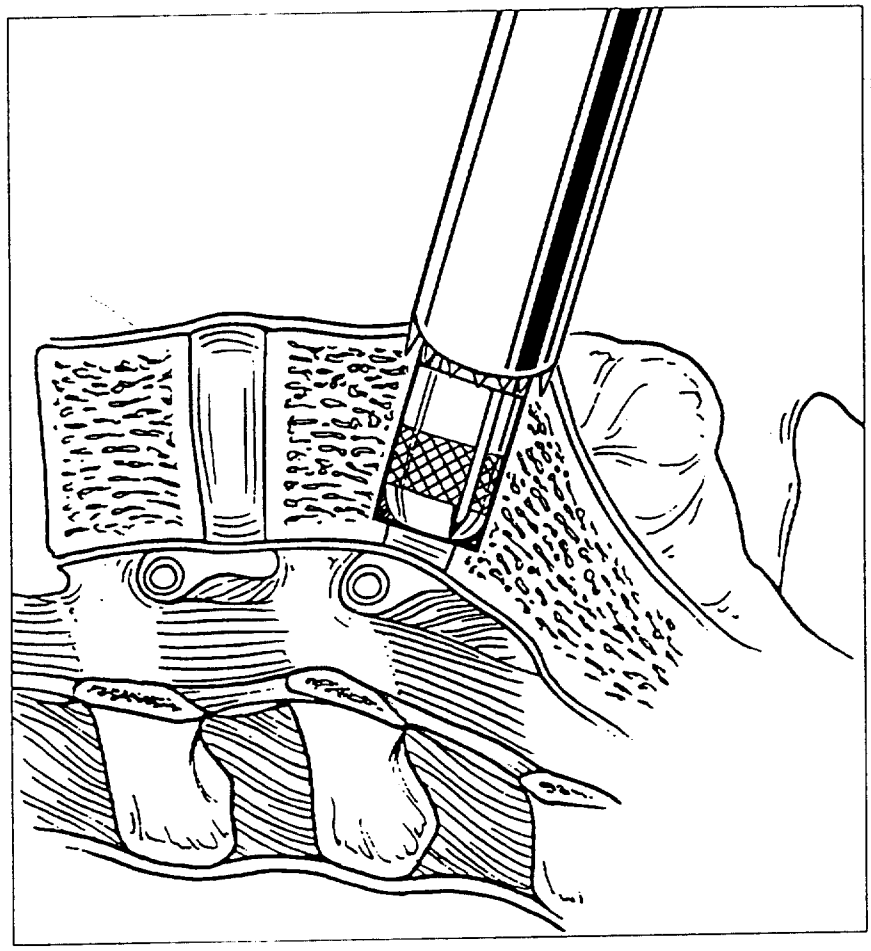

Figure 24

NECESSARY INSTRUMENTS

Bone Tap

While maintaining proper alignment, advance the Bone Tap through the Drill Tube and place the leading edge of the Tap within the hole. Apply a small amount of downward pressure to the Tap and rotate clockwise until the positive stop on the Tap contacts the top of the Drill Tube (Figure 25).

Unthread the Tap by rotating it counter-clockwise and remove it.

Caution: Do not attempt to advance the Tap beyond the point of contact with the Drill Tube. Further clockwise rotation of the Tap after contacting the stop will result in stripped bone threads.

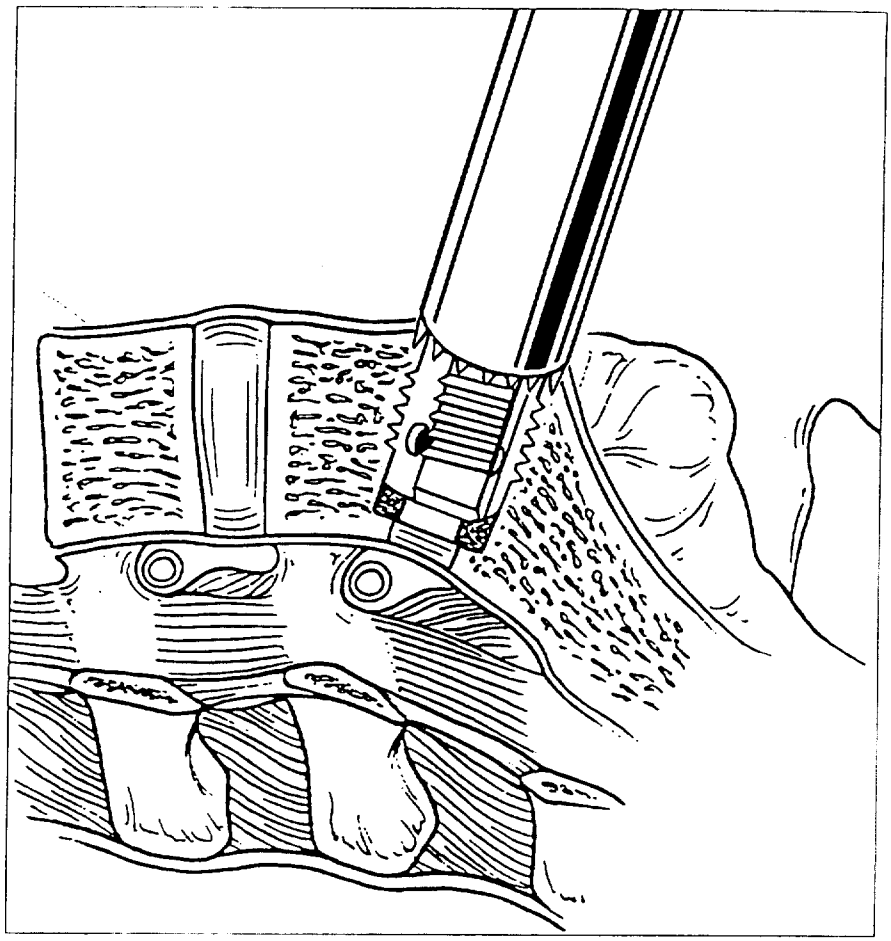

Figure 25

NECESSARY INSTRUMENTS

Implant Driver

Position the BAK implant onto the Implant Driver with the implant etching facing the handle. Secure the implant to the Implant Driver by advancing the press fit collet into the trailing chamber of the implant (Figure 26). Pack the leading chamber and large holes with morselized autograft bone. (Figure 27).

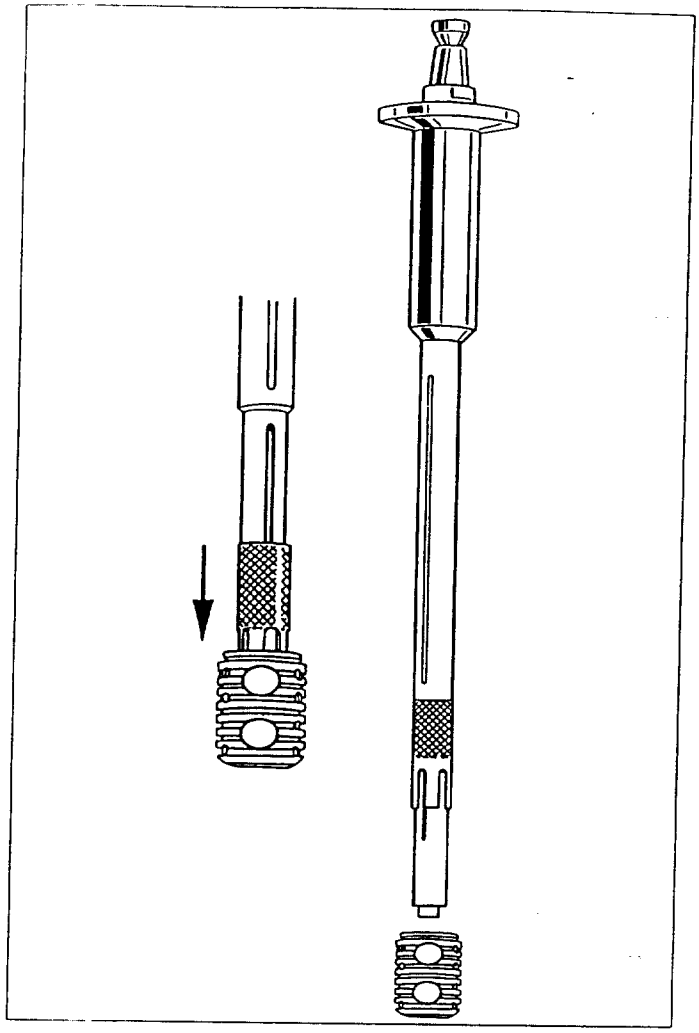

Figure 26

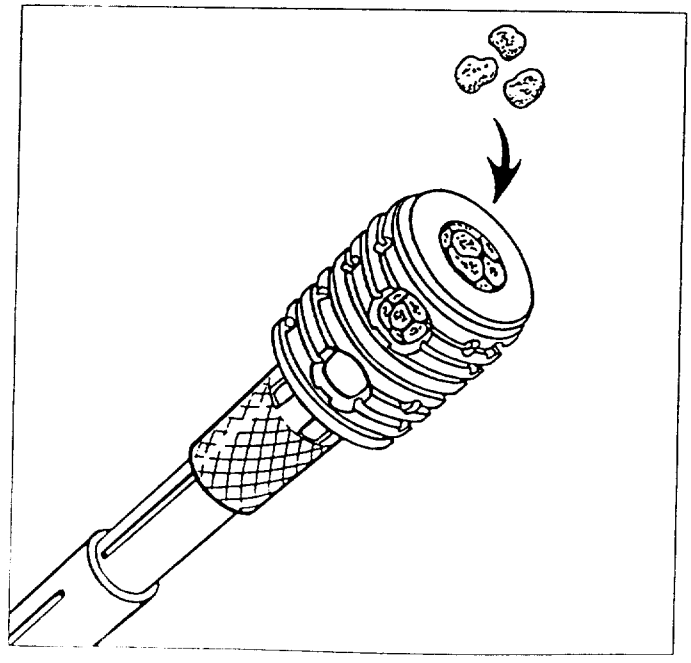

Figure 27

While maintaining the alignment angles utilized during drilling and tapping, insert the implant through the Drill Tube. Apply slight downward pressure and rotate clockwise to insert the implant. Advance the implant and Implant Driver until the positive stop on the Implant Driver contacts the top of the Drill Tube (Figure 28).

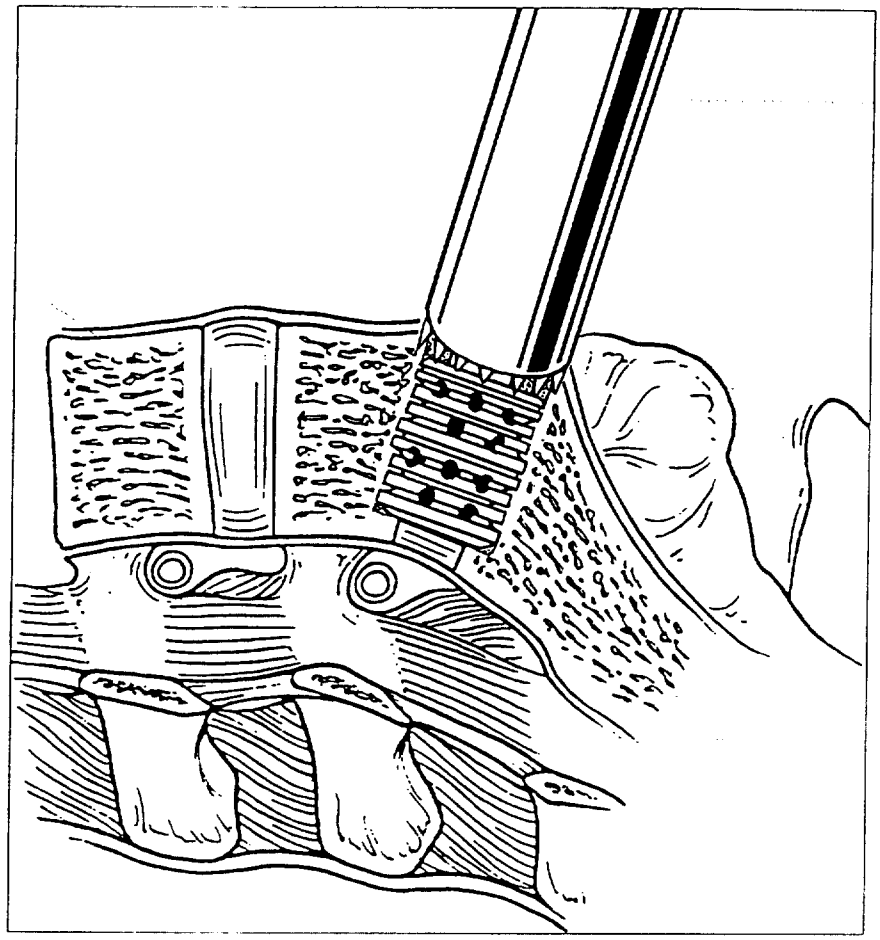

Figure 28

Proper implant orientation is achieved when the large holes are placed in a cephalad-caudal direction. This is attained when the Implant Driver T-handle is aligned parallel to the disc space.

Remove the Implant Driver by pulling straight up on the handle. This will cause the Implant Driver collet to release automatically. Remove the Drill Tube. Final implant placement is verified with a lateral radiograph. Implant placement should be recessed 3-4mm below the anterior margin of the vertebral bodies and show placement into the posterior third of the disc space

Caution: When the positive stop on the Implant Driver reaches the top of the Drill Tube, the implant should be properly placed. If additional advancement is desired, it can be accomplished provided space is still available at the bottom of the hole. After removing the Drill Tube, place the Implant Driver directly into the slot in the implant. Proceed to rotate the implant clockwise, with caution, under direct vision and/or radiographic imaging. It is critical that if additional insertion is attempted, the implant must always be advancing when rotated clockwise. Once the Implant contacts the bottom of the hole, continued clockwise rotation of the Implant Driver will result in stripped bone threads.

Assess the distance between the initial implant and the Distraction Plug to ensure medial shifting of the Drill Tube did not occur and adequate space for the second implant is still available.

Position the vein retractors appropriately. Thread the Distraction Plug Inserter into the Distraction Plug. Remove the Distraction Plug by rotating clockwise while pulling straight up (Figure 29). If this proves difficult, the Slap Hammer will fit on the Distraction Plug Inserter and can be used to impact upward and remove the Distraction Plug. Additional discectomy can be accomplished at this time.

The preparation of the remaining side is identical to that described in Steps 3-8.

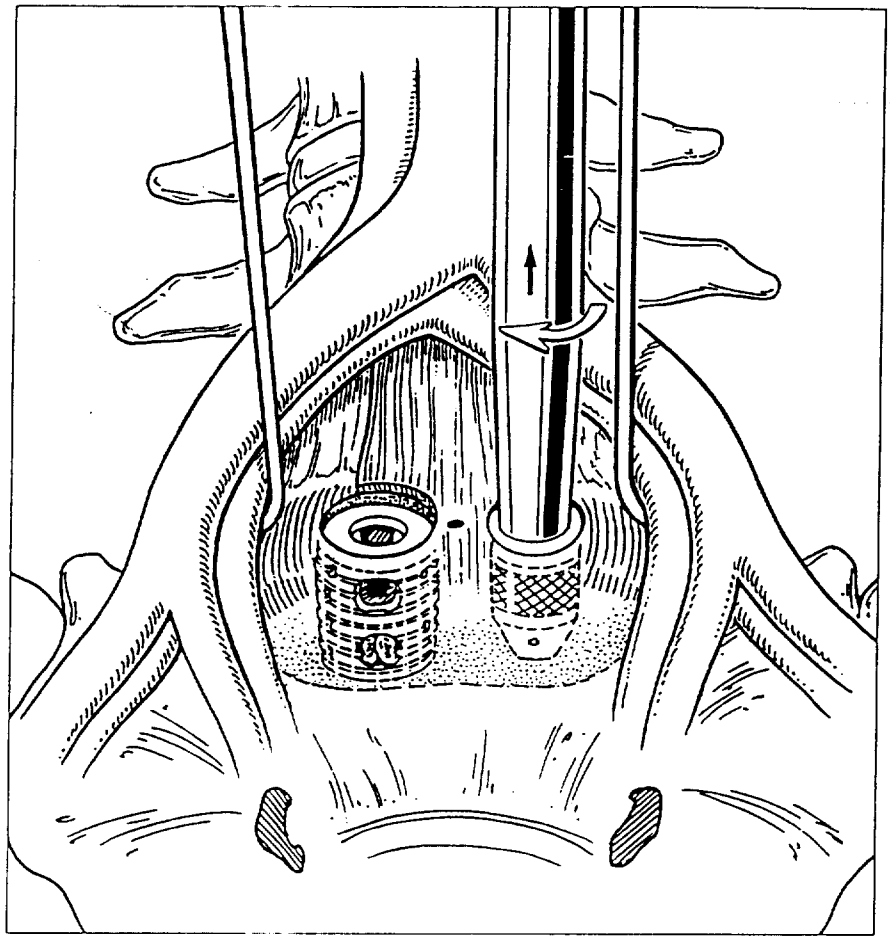

Figure 29

Note: If desired, additional bone can be packed between the implants. This is accomplished by placing bone into the second hole following tapping, packing it against the first implant, and then inserting the second implant.

Radiographic imaging will verify implant positioning within the intervertebral space.

Following confirmation of proper implant positioning and orientation (see note), the trailing chamber of both implants is packed with bone (Figure 30).

Note: Implants should be recessed 3-4 mm below the anterior cortical margin and have the leading edge penetrating into the posterior third of the motion segment. Additionally, the implant orientation is correct when the large holes are positioned in cephalad and caudal directions. This is indicated when on visual inspection it is noted that either the Quick Disconnect T-Handle orientation is parallel to the disc space or the long axis of the oval hole in the central web of an implant is parallel to the midline.

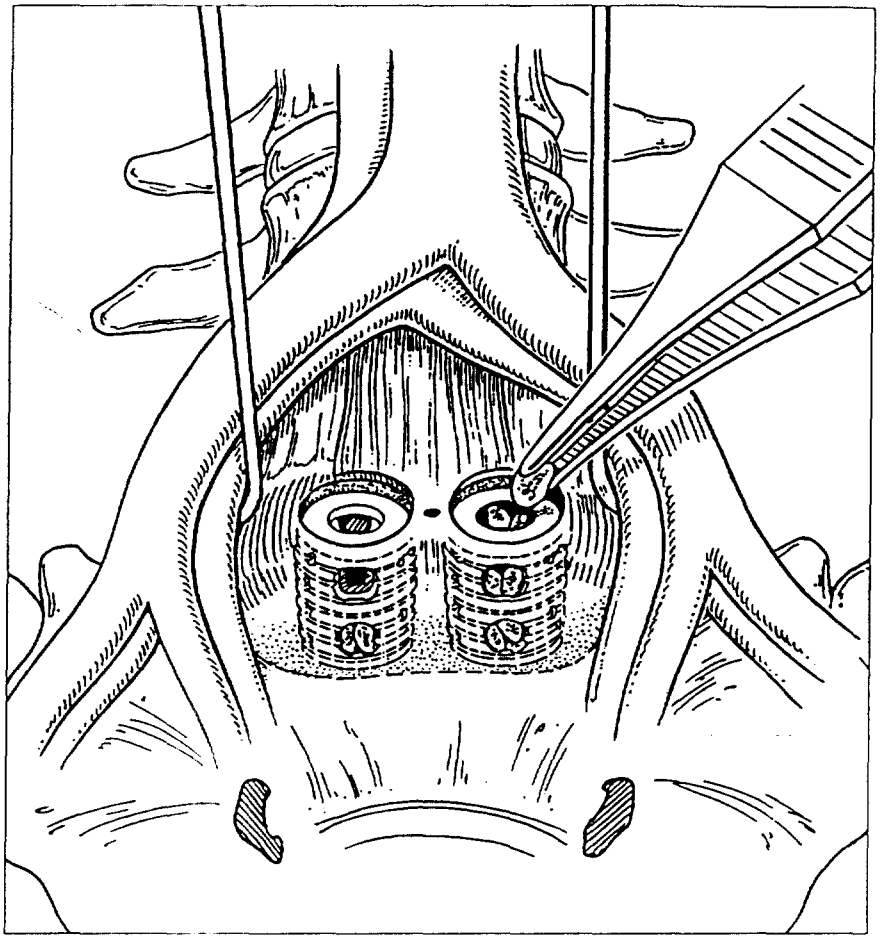

Figure 30

NECESSARY INSTRUMENTS

Endcap Inserter

Endcap placement is optional. The endcaps are designed to close off the trailing end of the implants and provide a smooth barrier to prevent the adhesion of soft tissues to the implant. In an anterior procedure, endcaps are utilized if an implant is not fully recessed and a smooth barrier is necessary to prevent vessel irritation.

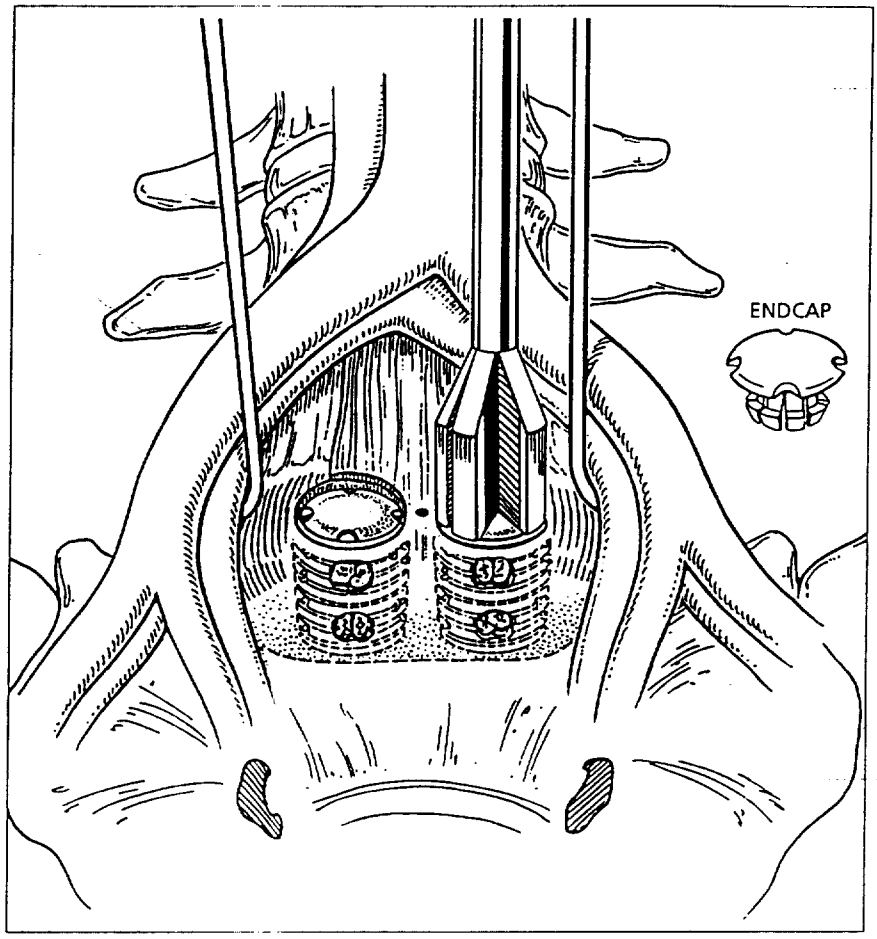

Figure 31

Attach the appropriate size endcap onto the Endcap Inserter by pressing the domed end of the endcap into the bottom of the instrument. The endcap attaches to the Endcap Inserter with a loose press fit. Following packing of the trailing chamber of the implants with bone, clear all tissue from the rim of the implant. The endcap is centered over the implant and lightly impacted into the implant (Figure 31). Proper positioning is achieved when the endcap spins freely but remains intact.

The retractors are removed and the incision is closed in the usual manner.

APPENDIX I ALTERNATIVE TAPPING AND IMPLANTING TECHNIQUE

Anterior Surgical Technique

If minimal discectomy is performed throughout the procedure, it may be desirable to more closely inspect the hole following reaming. To accomplish this, the Drill Tube is removed at the end of Step 5 and the following technique is followed in place of Steps 6-8 of the regular technique.

Step 6: Trial Implant Placement

In this instance Step 6 is no longer an optional step.

Following reaming, additional disc fragments are removed (Figure 32) and the Trial Implant is inserted into the hole (Figure 33). A visual reference point is selected corresponding to the trailing edge of the Trial Implant. Since the implant and Trial Implant are the same length this reference point indicates the depth to which the implant may be screwed in without jeopardizing bone thread integrity.

Remove the Trial Implant.

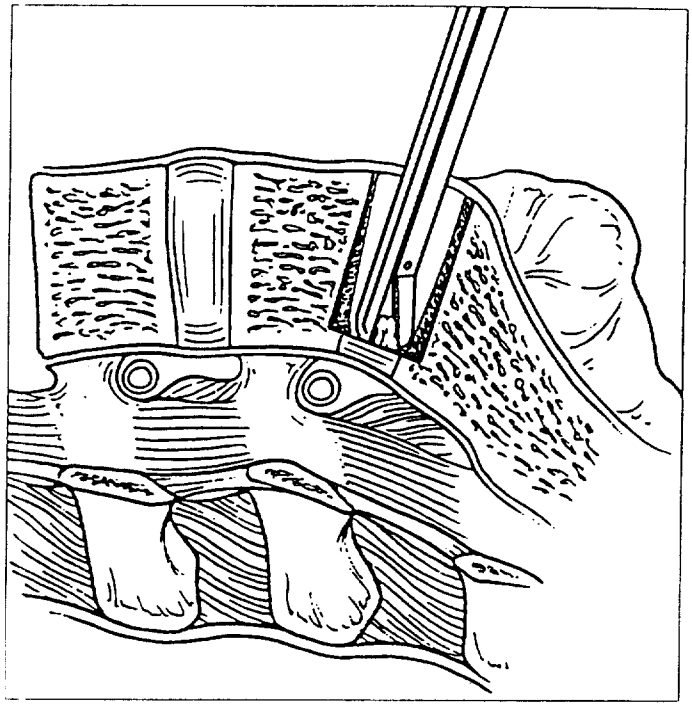

Figure 32

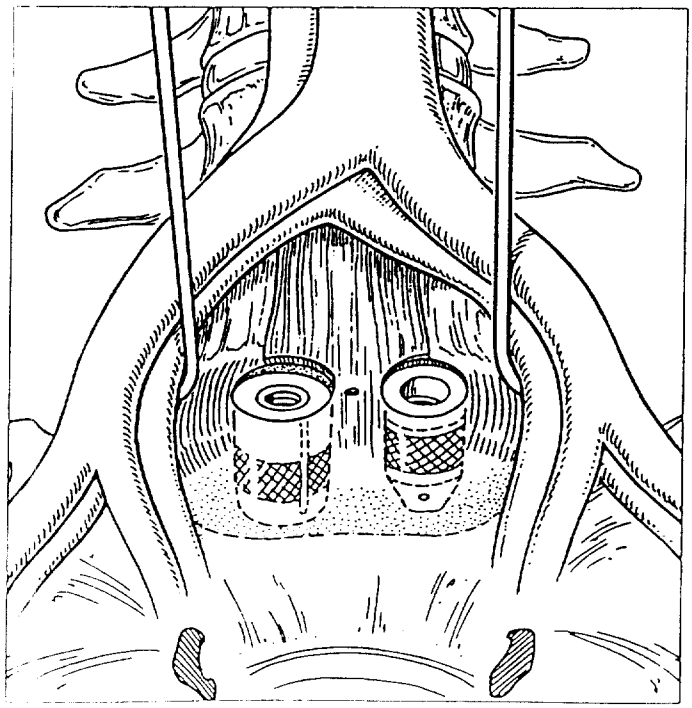

Figure 33

Step 7: Bone Tapping

Place the leading edge of the Bone Tap directly into the hole and position the instrument shaft at the angles previously used to perform the drilling. Rotate the Tap clockwise to cut the first few threads into the bone (Figure 34). Unthread and remove the Tap.

Step 8: Implanting the BAK

Place the implant on the Implant Driver and pack it appropriately with bone. Insert the implant directly into the tapped hole. Apply slight downward pressure and rotate clockwise to insert the implant. Advance the implant until the trailing edge reaches the reference point predetermined by the Trial (Figure 35).

Note: If desired, additional bone can be packed between the implants. This is accomplished by placing bone into the second hole following tapping, packing it against the first implant, and then inserting the second implant.

Insert the second implant and pack the trailing chamber with bone.

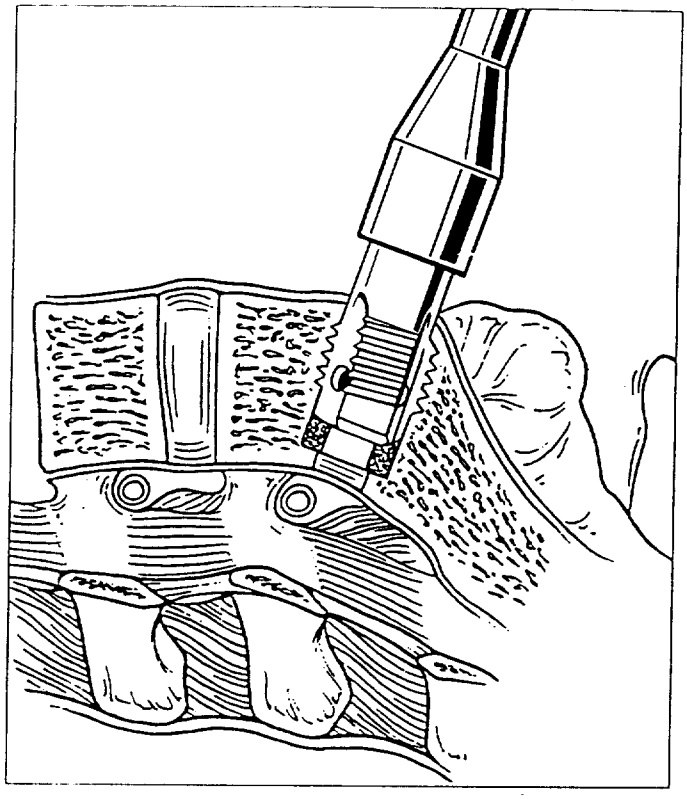

Figure 34

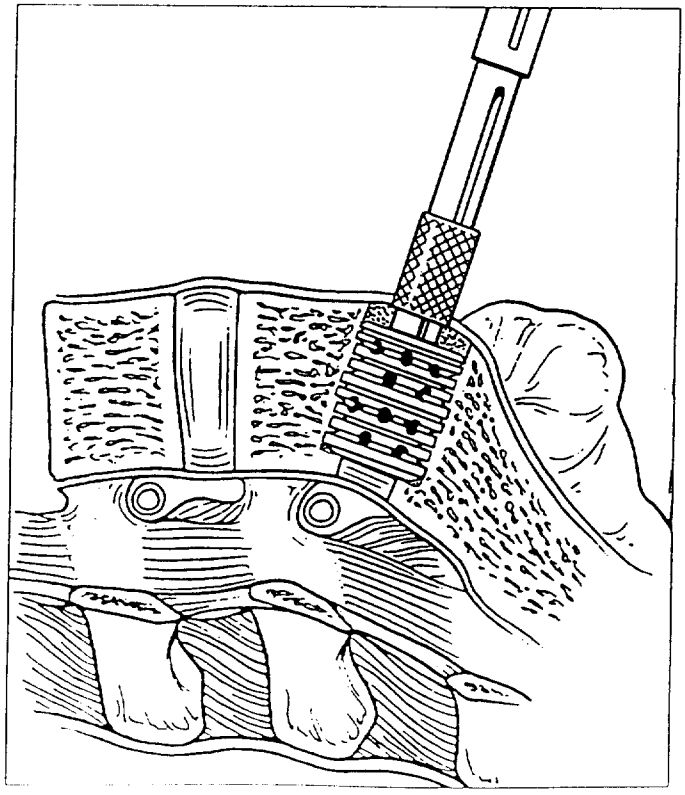

Figure 35

Concave Endplates:

It is not uncommon for patients with exaggerated concave endplates to present for surgery. This patient population requires a minor modification to the BAK procedure to ensure that proper implant alignment, vertebral purchase and lumbar lordosis are achieved and maintained.

Prior to placement of the Distraction Plugs, it is necessary to remove the large marginal osteophytes at the location of the 8mm drilling sites. This can be easily accomplished with a 1/4 inch osteotome or Kerrison rongeur.

This step is necessary to achieve an accurate representation of the disc height which needs to be bridged by the implant.

Spondylolisthesis:

It is not uncommon for patients with Grade I spondylolisthesis or retrolisthesis to present for surgery. This population requires a minor modification to the BAK procedure to ensure proper implant alignment and vertebral purchase are achieved.

If the slip is mobile, correction of the spondylolisthesis can many times be affected by distracting the motion segment incrementally on one side and then the other until the proper Distraction Plug is identified. If this is possible and complete reduction is achieved, proceed with the implantation in the usual fashion.

If the spondylolisthesis does not fully reduce, the Drill Tube and Drill Tube Sheath may not sit evenly over the anterior margin of the disc space. Rather, they will angle such that drilling would cut much more out of one vertebra than the other.

To correct this situation, following impaction of the Drill Tube, use lateral radiographs to modify the angle of the Drill Tube to be parallel with the endplates of the disc. After realignment, gently strike the top of the tube to firmly reseat the teeth.

Inadequate Vessel Mobilization:

A scenario which may arise at the L4-5 level is inadequate great vessel mobilization to place the right side implant. In these instances a single implant may be placed in the midline. When a single implant must be used, select the largest size which will fit within the anterior/posterior dimension. This is typically a 17x24 or 17x28.

Step 1

Following exposure of the anterior aspect of the spine, a pin or needle is inserted approximately in the midline. An anterior-posterior radiograph is taken to verify the location of the midline. A size 15 scalpel blade is used to slit the annulus at the indicated spot on the disc. Development of this landmark is critical to ensure accurate midline implant placement.

Step 2

The 8mm Drill is placed into the 8mm Drill Tube. This protects soft tissue while drilling and provides a positive stop. Taking care to retract the vessels appropriately, insert the drill tip into the slit and drill until the positive stop on the drill meets the top of the Drill Tube.

Note: Using a pituitary rongeur and/or small curette, nucleus material can be removed through the drill hole. Additional annulus may also be removed, but care should be taken to remove it equally around the original 8mm hole. Avoid elongation of the hole and decortication of the endplate as it may affect Distraction Plug or Guide Pin placement and subsequent alignment.

Step 3

A small Distraction Plug is impacted into the hole and tested. If it pulls out easily, incrementally larger plugs are used until significant resistance is met while extracting the plug.

After identifing the correct Distraction Plug size, Remove the Distraction Plug.

Step 4
Thread a Guide Pin equivalent in size to the Distraction Plug onto the Drill Tube Guide.

Impact the Drill Tube Guide and Guide Pin into the 8mm drill hole. This will center the Drill Tube Guide over the disc.

Assemble the Drill Tube Sheath onto the Drill Tube and slide the assembly over the Drill Tube Guide. Use lateral radiographic imaging and visual inspection to ensure the Drill Tube is properly aligned. Secure the anchoring teeth of the Drill Tube into the vertebral bodies and remove the Drill Tube Guide.

To prevent disc material from retropulsing, pass the Pituitary Rongeur through the Drill Tube and grasp any remaining disc fragments that may be at the bottom of the hole. Care should be taken to ensure the posterior annulus is not penetrated with the Pituitary Rongeur.

Step 5
If a 15 x 20 or 17 x 24 BAK implant is to be used, slide the Short Series Spacer onto the top of the Drill Tube prior to reaming, tapping and implanting.

Step 6 *(Optional)*
Thread the appropriate Trial Implant onto the Distraction Plug Inserter. Insert the Trial Implant through the Drill Tube and into the prepared hole. A lateral radiographic image is taken to verify reaming depth and implant position. The Trial Implant should be recessed 3-4mm below the anterior margin of the vertebral bodies and show placement into the posterior third of the disc space.

Remove the Trial Implant.

Step 7

Advance the Bone Tap through the Drill Tube until the positive stop on the Tap meets the top of the Drill Tube.

Caution: Do not attempt to advance the Tap beyond this point. Further clockwise rotation of the Tap after contacting the stop will result in stripped bone threads.

Step 8

Place the implant on the Implant Driver and pack the leading chamber appropriately with bone. Insert the implant through the Drill Tube. Apply slight downward pressure and rotate clockwise to insert the implant. Advance the implant and Implant Driver until the positive stop on the Implant Driver contacts the top of the Drill Tube. Align the implant in the usual fashion and pack the trailing chamber with bone.

Note: Inadequate vessel mobilization is the primary reason for utilizing a single implant. If other anatomical or pathological abnormalities arise which preclude use of bilateral implants, this same technique is followed.

Implant Contact:

If alignment has been compromised, the threads on the implants may mesh together during insertion. If this occurs, there is a possibility that as the second implant is screwed in, it will unscrew the first implant.

If this occurs, position the first implant appropriately and hold it stationary by inserting a small osteotome in the central slot. This will prevent the first implant from unscrewing as the second implant is screwed in.

Bone Thread Stripping:

The BAK implants require thread purchase within the vertebral bodies to achieve optimal stability. As previously stated, great care should be taken not to damage the bone threads during implantation.

If damage should occur and the implant is deemed unstable, corrective action to regain a stable condition is recommended. The BAK implant sizing has been established with incremental increases of 2.0mm from one size to the next.

If the bone threads become stripped, the action which caused the stripping will create a hole equivalent in size to the minor diameter of the next larger diameter implant.

In this instance, the reaming depth is inspected with a Trial Implant to ensure the larger implant can be positioned behind the anterior cortical margin. If it does not fit, careful retraction of the vessels is accomplished. The Final Reamer is then directly introduced and carefully advanced under radiographic control until the Trial Implant fits.

Following Trial Implant inspection and subsequent additional reaming, where necessary, the larger Tap is advanced directly into the hole to cut the first few threads. The larger implant is then assembled onto the Implant Driver, packed with bone, and threaded into the hole.

In situations where the 17mm implants were used and stripping occurred, a bone dowel of 20mm in diameter is necessary to fill the hole as the 17mm diameter is the largest BAK implant available.

The following table illustrates the implants necessary to re-establish stability following bone thread stripping:

Implant Stripped	Recovery Device
13 x 20mm	15 x 20mm
15 x 20mm	17 x 24mm
15 x 24mm	17 x 24mm
17 x 24mm	20mm bone dowel
17 x 28mm	20mm bone dowel

APPENDIX III POSTOPERATIVE CARE

Anterior Surgical Technique

Immediate postoperative care includes:

- Routine monitoring of vital signs and neurological status.
- Administration of appropriate pain medication.
- If nasogastric tubes and/or Foley catheters are utilized, discontinue within 24 hours post-op.
- The patient is encouraged to ambulate as tolerated the day of surgery. The use of a brace is at the discretion of the surgeon.
- Diet is restricted to small amounts of liquids until bowel sounds are heard. Diet is then advanced as tolerated.
- Patients should be instructed to restrict activity until advised by their surgeon.

The BAK system utilizes slight variations in drill tube combinations when implants are inserted from an anterior vs. posterior approach.

These variations are necessary to minimize the retraction of neural structures during posterior implantation of the BAK.

Posterior

Implant size	Drill Tube	Drill Tube Guide	Sheath
13mm	4010-1425	4010-1424	4010-1350
15mm	4010-1625	4010-1624	4010-1550
17mm	4010-1825	4010-1824	4010-1750

Anterior

Implant size	Drill Tube	Drill Tube Guide	Sheath	Drill Tube Sleeve
13mm	4010-1625	4010-1624	4010-1351	4010-1326
15mm	4010-1825	4010-1824	4010-1551	4010-1526
17mm	4010-2025	4010-2024	4010-1751	4010-1726

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U.S.A
Telephone: 612.832.5600 or 1.800.655.2614
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POSTERIOR

Surgical Technique

BAK™ Interbody Fusion System

SPINETECH®

TABLE OF CONTENTS

Posterior Surgical Technique

INTRODUCTION

Posterior Surgical Technique

The Spine-Tech BAK implant is a fenestrated, threaded, cylindrical, titanium alloy device to be inserted within the intervertebral disc space. The implant is coupled with instruments designed to reproducibly prepare the bone bed, protect surrounding tissues and safely position the implants. The system is designed to provide an immediately stable motion segment to allow fusion and relief of symptoms.

Design features of the BAK implant include:

- Vertebral distraction evenly tenses the remaining annulus creating a tension band around the implants
- Threads engage the vertebral body to enhance resistance to shear forces
- "Keystone" effect resists rotational forces
- Internal ribbing to enhance fatigue strength
- Lordosis maintained through vertebral body support
- Foraminal volume and area are increased through distraction providing decompression

Design features of the BAK instruments include:

- Drill tubes aid in retraction and protection of vital structures during implantation
- Positive stops prevent overdrilling
- Drill Tube teeth ease tube docking and prevent instrument migration
- Alignment Guides facilitate accurate implant insertion and spacing

Indications, contraindications, potential adverse effects and precautions are referenced in the package insert.

RADIOGRAPHIC TEMPLATING

Posterior Surgical Technique

Radiographic templating assists with selecting appropriate implant and Distraction Plug sizes which maximize implant endplate coverage and create proper vertebral distraction and annular tension. Selection of the proper size BAK implants is critical for optimum results.

Radiographic templates (Figure 1) are available in 15% magnification for use with plain x-rays and 50% to 80% reductions for MRI and CT scans. Templates include the following information:

- Implant size and distraction plug size chart
- Lateral BAK implant and associated drilling representations
- Lateral distraction plug representations
- Anterior/Posterior implant representations
- Magnification or reduction scale

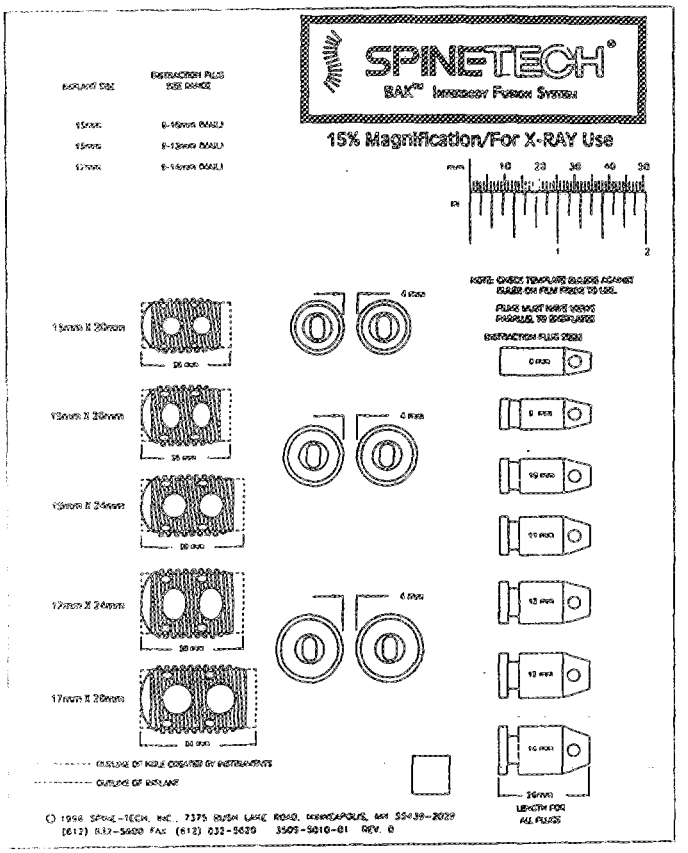
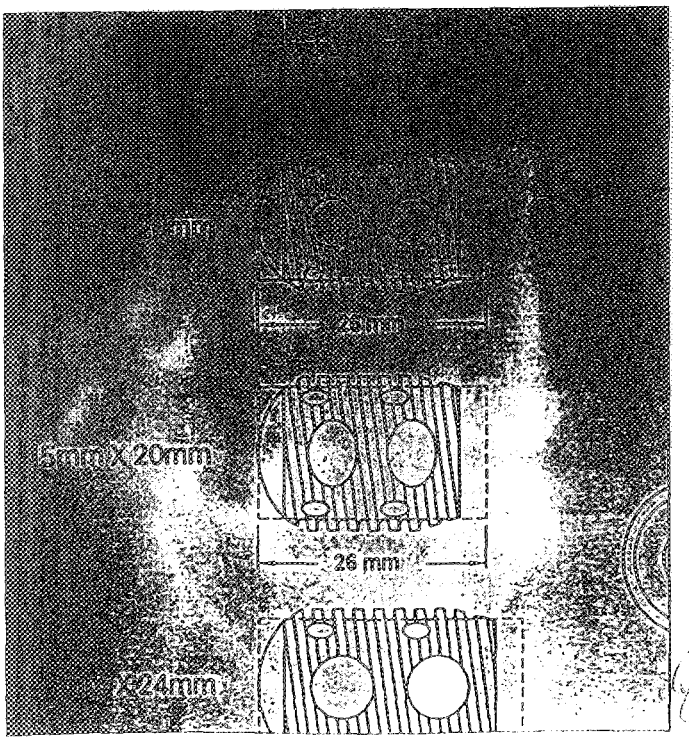


Figure 1

Step 1

The proper implant length is assessed with a lateral x-ray. The red dotted lines, representing the final reaming depths, and lateral implant representations are overlaid on the affected disc (Figure 2). Select the maximum reaming depth and implant size which is safely contained within the anterior and posterior vertebral margins.

This assessment will typically reduce the implant selections to one length and two diameters.



Step 2

On the same lateral x-ray, overlay the Distraction Plug outline on an adjacent healthy disc (Figure 3). The Distraction Plug which bridges the space is an indication of the potential distraction of the affected motion segment.

Step 3

Compare the implant diameters indicated in Step 1 with the Distraction Plug size indicated in Step 2 using the Implant Size/Distraction Plug Size Range chart in the upper left hand corner of the template.

If the Distraction Plug size indicated in Step 2 is not within the range listed for the smaller implant diameter, the larger implant diameter is selected. If it is, the A/P x-ray is used to further assess the correct implant size.

The Implant Size/Distraction Plug Size Range chart is recreated below.

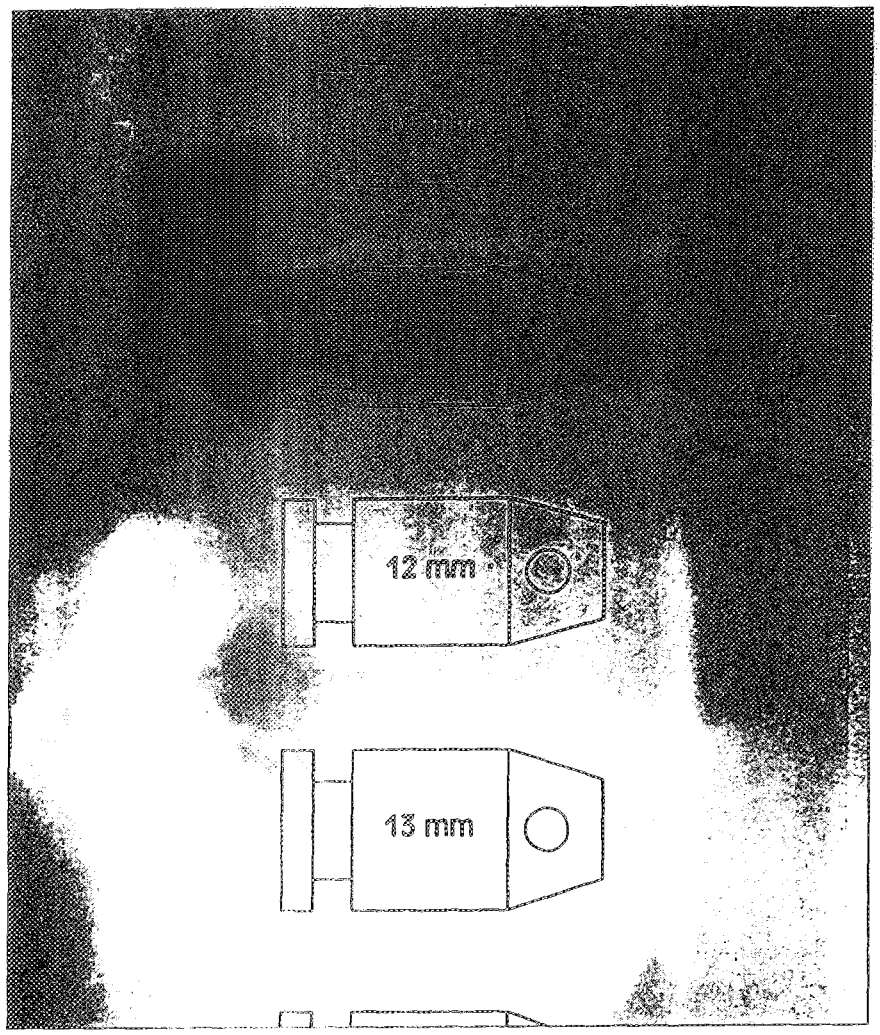


Figure 3

Implant Size	Distraction Plug Size Range
Size 13mm	9-10mm (max.)
Size 15mm	9-12mm (max.)
Size 17mm	9-14mm (max.)

Note: As a general rule, for the implant to obtain adequate purchase into the vertebral bodies, it must be at least 3mm larger than the Distraction Plug used.

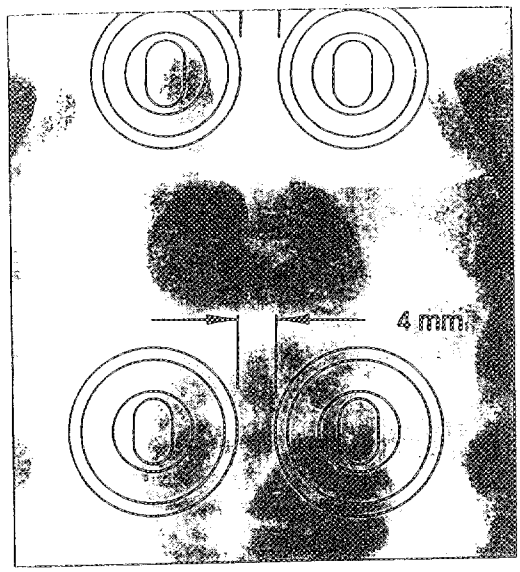


Figure 4

Step 4

The appropriate implant diameter is further assessed or confirmed by overlaying the A/P BAK outlines of the implant diameters determined in Steps 1 and 2, over the A/P x-ray. Center the images over the superior most vertebral body to be fused (Figure 4). The largest implant representations which fit within the lateral margins indicate the implant size to be used.

An MRI/CT axial cut reflecting the smallest endplate of the affected disc can help determine implant size. To select the proper BAK MRI/CT template, match the scale on the template to that of the scan (Figure 5). Use the bilateral axial template images to assess the largest outlines which are safely contained within the disc margins (Figure 6).

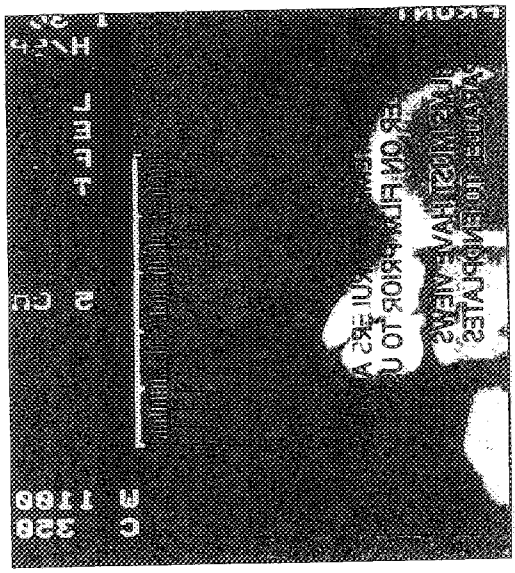
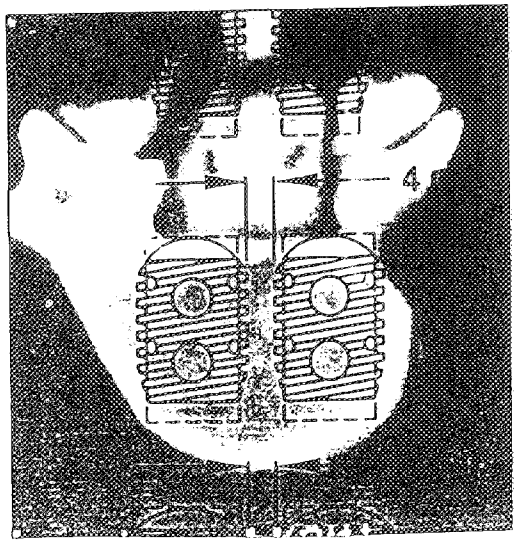


Figure 5

Caution: When using the MRI/CT templates, it is critical that the transverse vertebral representations are parallel to the endplates. If they are not, the images will be oversized and may lead to selection of an implant and associated drilling depth which is too long.

Note: Templating provides an estimate of implant and distraction plug size. Final sizes will be determined intraoperatively.

After implant size selection is complete, the common instruments and the instruments specific to the selected implant size are removed from the instrument trays.



The patient is placed in a 90 degree kneeling-sitting position on an Andrews or similar frame to maintain lumbar lordosis and affect abdominal decompression to reduce epidural and venous pressure (Figures 7 and 8). Spinal, general or progressive local anesthesia is administered. The skin is incised in the midline above the level(s) to be fused. The paravertebral muscles are then split and retracted laterally to the outer edge of the facet joints. A laminotomy of sufficient size and/or partial or total facetectomy is performed to accommodate the implants and instruments. The bone is retained and morselized to increase the volume of the bone graft available to pack the implants. When necessary, additional decompression is performed.

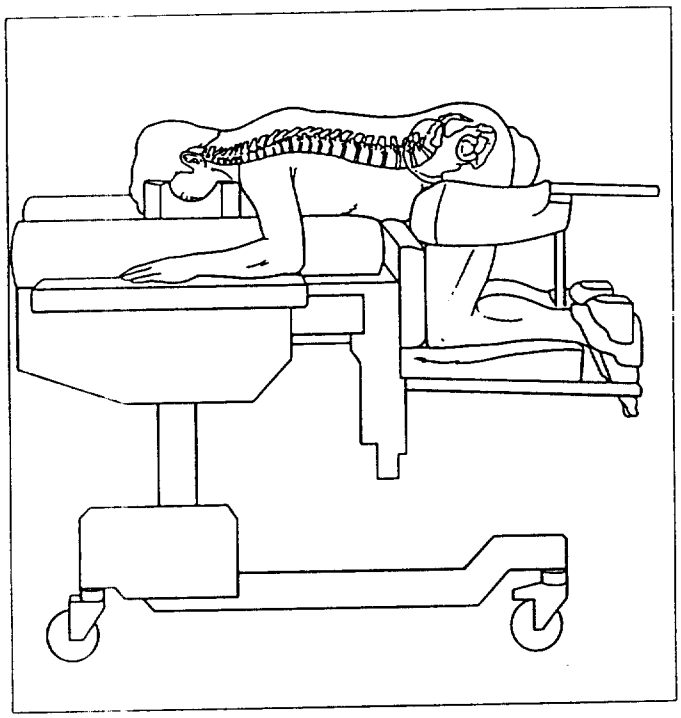


Figure 7

The epidural veins are identified, cauterized with bipolar electro-cautery and divided and/or packed away prior to full mobilization of the dura to the midline. As with any PLIF operation, the dura and nerve roots above and below must be identified, mobilized and protected from injury during the drilling and instrumentation. Use of the operating microscope or loops greatly facilitates the safety of the exposure.

If bone graft is to be obtained from the iliac crest, it should be harvested prior to nerve retraction to minimize the duration of retraction placed on the nerve roots and dura. About five to seven cc's of compacted cancellous graft is necessary for each implant.

Note: The presence of conjoined nerve roots or other anomalies and pathologies may render the posterior interbody fusion impossible by this or any other PLIF method.

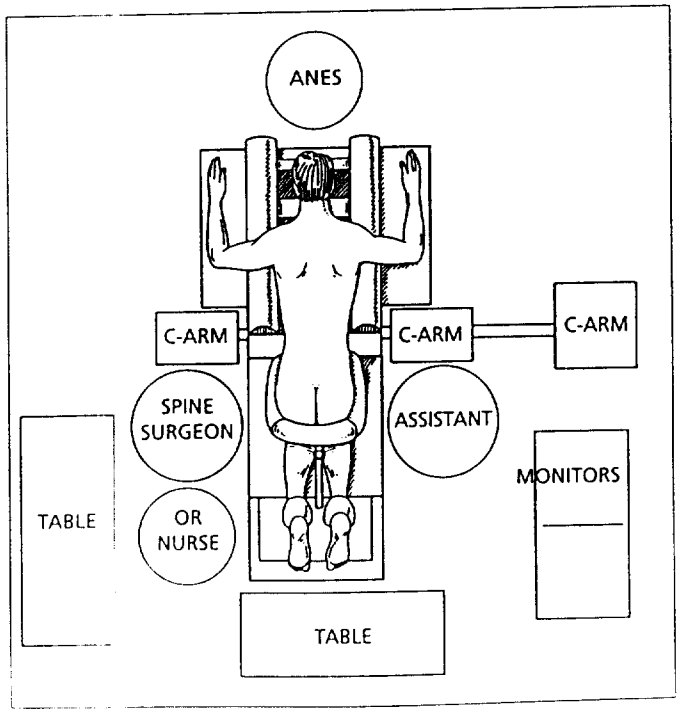


Figure 8

NECESSARY INSTRUMENTS

Starter Alignment Guide
Alignment Guide Handle

The Starter Alignment Guide is used to establish drilling locations and spacing for the BAK implants within the intervertebral space. It is designed to place the implants 4mm apart.

Initially, place the plastic portion of the Starter Alignment Guide on the handle with the prongs pointing towards the handle. The flat surface acts as a template indicating the exposure necessary to place the size specific instruments and implants (Figure 9). Any bone dissected from the lamina, facets and spinous process to create access can be preserved for use as bone graft.

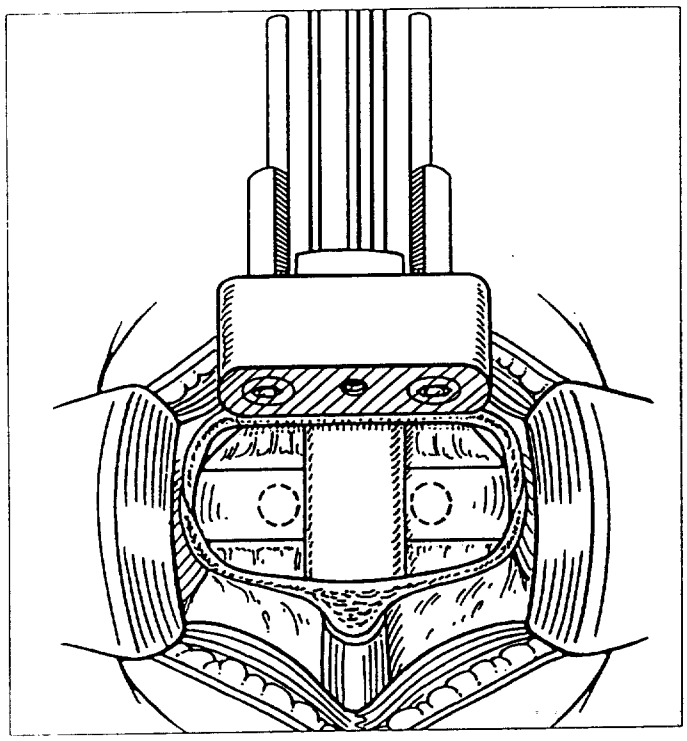


Figure 9

The handle of the Starter Alignment Guide is then secured to the guide with the prongs pointing away from the handle. The prongs are placed on either side of the cauda equina such that they are at mid-disc height and equidistant from the midline. Mark the points by cutting a small slit in the disc with a size 15 scalpel blade (Figure 10). These marks indicate the locations for implant insertion.

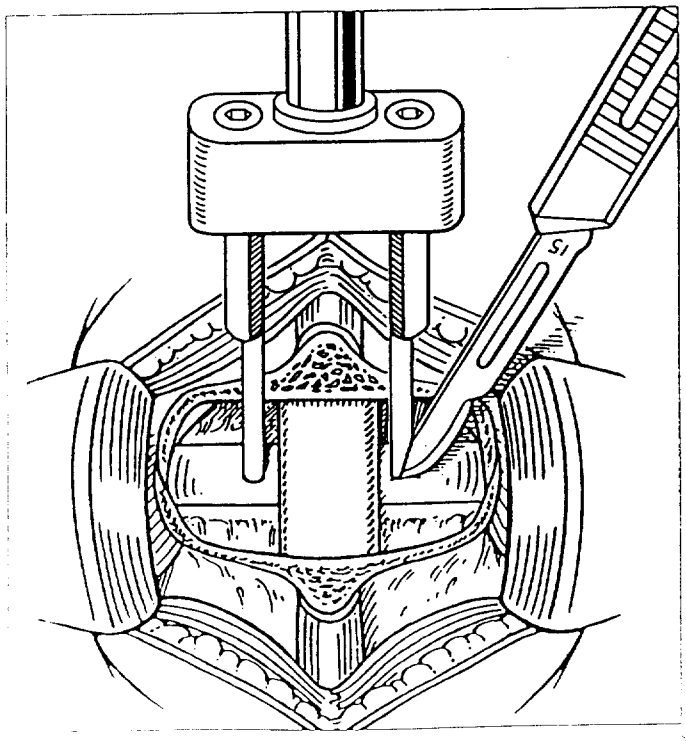


Figure 10

The Starter Alignment Guide may be pressed ventrally into the disc until the positive stops on the prongs contact the disc. With radiographic assessment, the Starter Alignment Guide prongs can be used to assess final reaming depth and angle (Figure 11). See the chart below for prong lengths and the corresponding maximum reaming depths:

Guide Size	Prong Length	Final Maximum Reaming
13	26 mm	26 mm
15	30 mm	30 mm
17	34 mm	34 mm

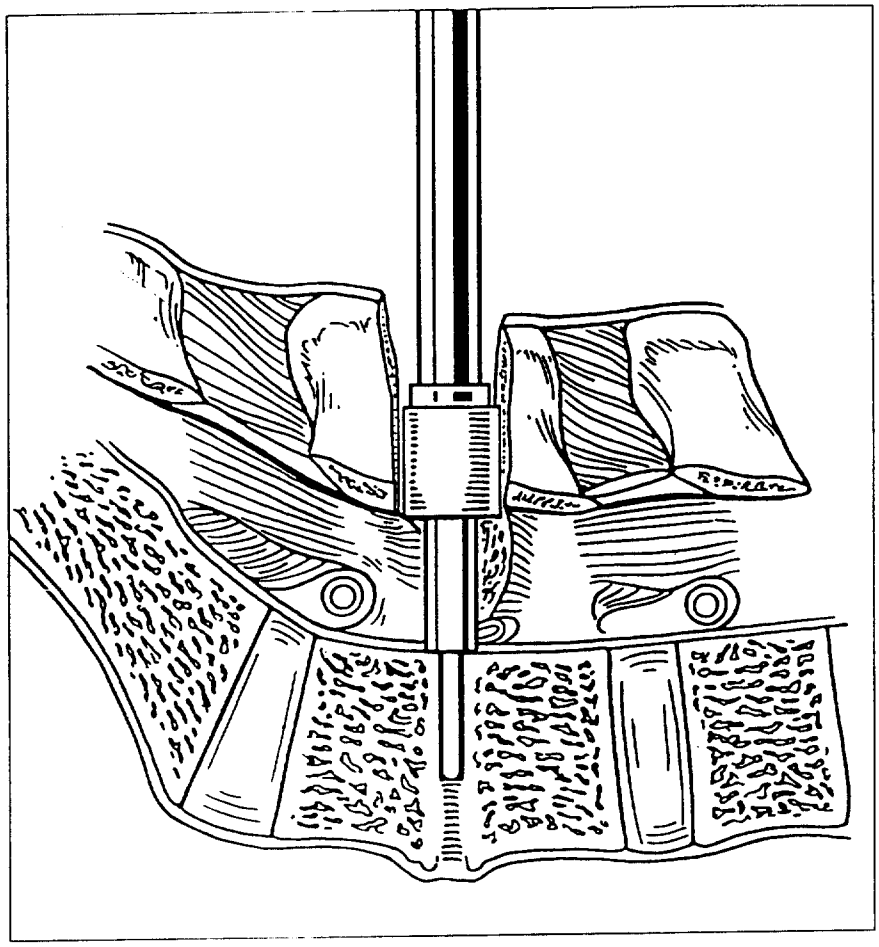


Figure 11

NECESSARY INSTRUMENTS

8mm Drill
8mm Drill Tube

The 8mm Drill is used to increase the size of the small slits created by the scalpel blade and begin the discectomy required to place the implants.

The 8mm Drill is placed into the 8mm Drill Tube. This protects soft tissue while drilling and provides a positive stop. Taking care to retract the nerves appropriately, insert the drill tip into the slit and drill until the positive stop on the drill meets the top of the Drill Tube. Repeat this on the opposite side (Figure 12).

Note: Using a pituitary rongeur and/or small curette, nucleus material can be removed through the drill holes (Figure 13). Additional annulus may also be removed, but care should be taken to remove an equal amount around the original 8mm holes. Avoid elongation of the holes and decortication of the endplate as it may affect Distraction Plug or Guide Pin placement and subsequent alignment.

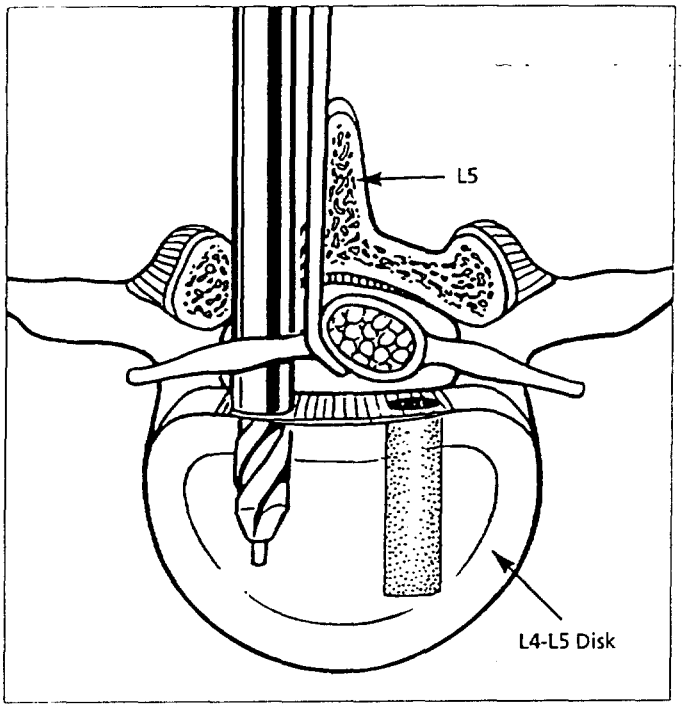


Figure 12

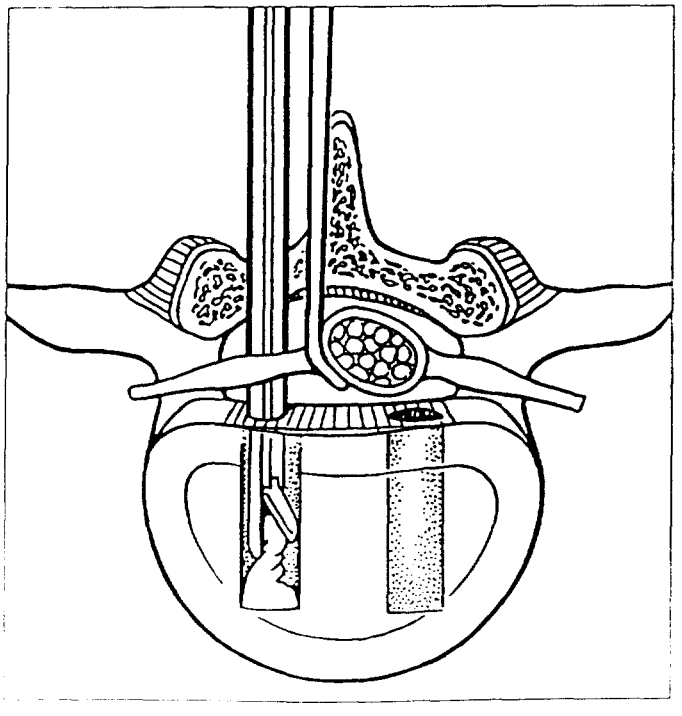


Figure 13

NECESSARY INSTRUMENTS

Distraction Plug Inserter
Distraction Plugs

Distraction Plugs are used to distract the vertebral bodies and apply tension to the annulus prior to vertebral reaming.

Attach a relatively small Distraction Plug onto the Distraction Plug Inserter. Retract the nerve root and dura with thin dural retractors and impact the Distraction Plug into one of the 8mm drill holes (Figure 14). The Distraction Plug is impacted until the back edge of the plug is slightly recessed below the posterior margin of the disc (Figure 15). Check the annular tension by pulling straight up on the Distraction Plug Inserter. If the Distraction Plug pulls out easily, repeat this procedure using incrementally larger Distraction Plugs until the annulus is sufficiently taut. This is indicated when significant resistance is met during Distraction Plug removal.

Once the correct Distraction Plug is identified, assess the disc space angle by noting the angle of the Distraction Plug Handle. This angle is critical as all future drilling, tapping and implantation steps need to be performed at this angle. Remove the handle, leaving the Distraction Plug in place.

Note: As a general rule, for the implant to obtain adequate purchase into the vertebral bodies, it must be at least 3mm larger than the Distraction Plug used. See chart below.

Implant Size	Distraction Plug Range
Size 13mm	9-10mm (max.)
Size 15mm	9-12mm (max.)
Size 17mm	9-14mm (max.)

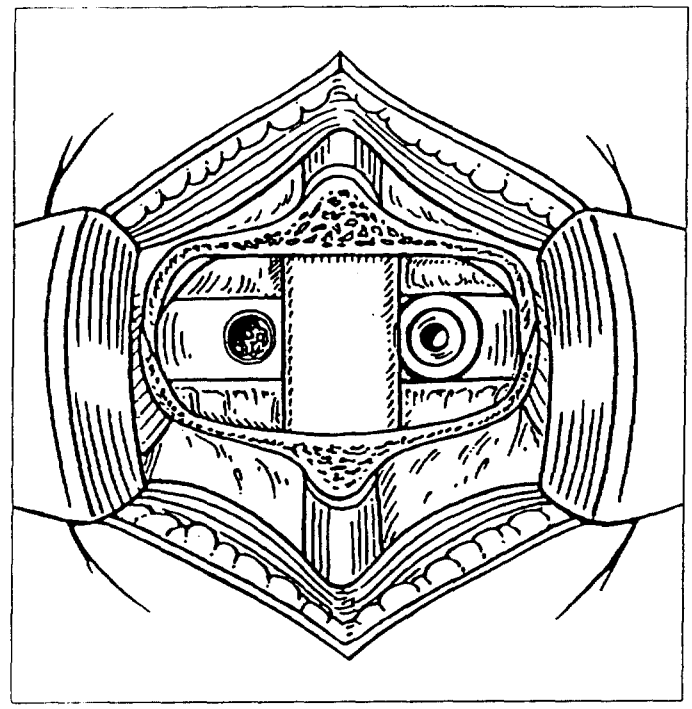


Figure 14

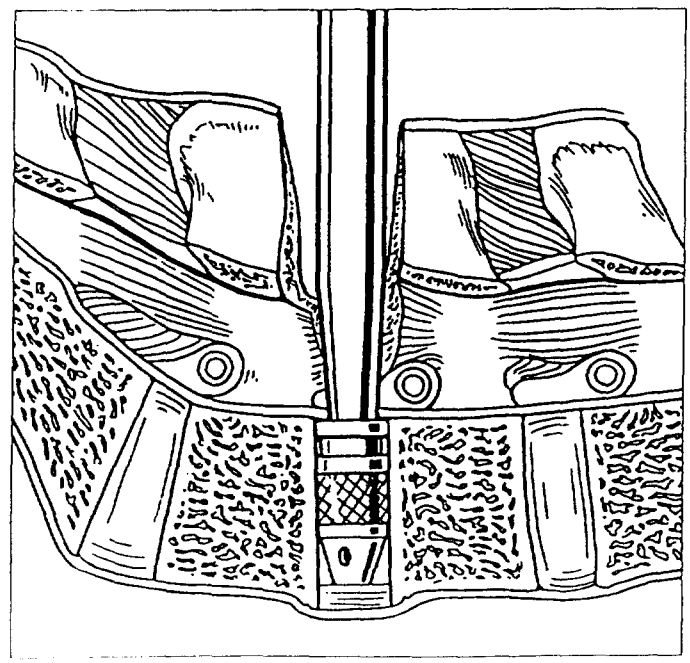


Figure 15

89

NECESSARY INSTRUMENTS

Drill Tube Guide
Drill Tube
Guide Pin
Posterior Drill Tube Sheath
Distraction Plug Inserter
Alignment Guide Handle
Slap Hammer

On the side opposite to the Distraction Plug, carefully insert the Posterior Drill Tube Sheath under the axilla of the nerve root using thin dural retractors (Figure 16). Center the sheath over the 8mm drill hole with the sheath's lip under the nerves. The Distraction Plug Inserter is screwed into the side of the Drill Tube Sheath to aid in stabilization of the instruments.

Note: A visual inspection down the sheath is made to ensure the nerve root and dura are retracted. Once the inspection is complete and the nerves are cleared, remove the retractors, if possible, to prevent excessive tension upon the dura.

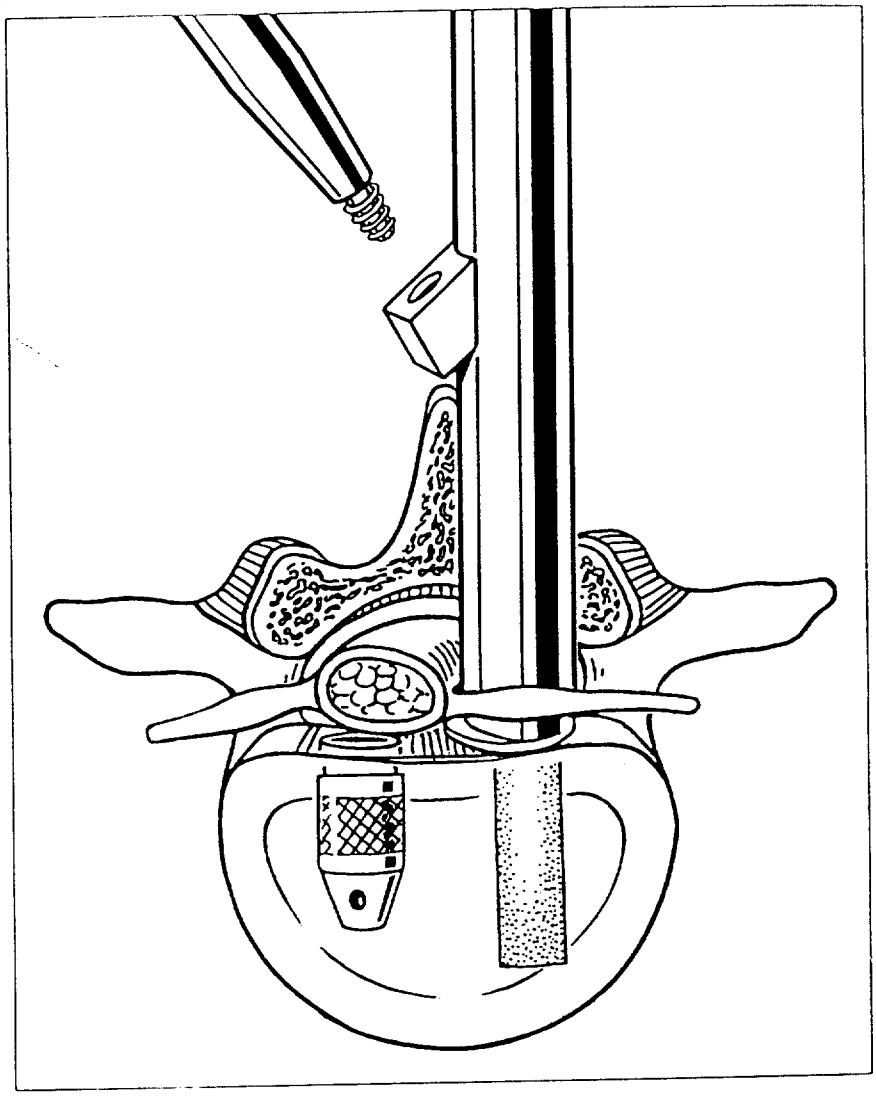


Figure 16

Thread a Guide Pin, equivalent in size to the Distraction Plug onto the Drill Tube Guide. Insert the Drill Tube Guide through the Sheath and place the Guide Pin into the 8mm hole (Figure 17).

The Drill Tube is then inserted over the Drill Tube Guide and into the Drill Tube Sheath.

Using lateral radiographic imaging, ensure the superior and inferior sides of the Drill Tube are aligned parallel to the vertebral endplates. Additionally, visually inspect to ensure the Drill Tube is perpendicular to the coronal plane of the disc. If a convergent angle is placed on the Drill Tube, it may cause the implants to contact one another. Conversely, a divergent angle may cause the implants to break out of the disc laterally, disrupting the annular tension band.

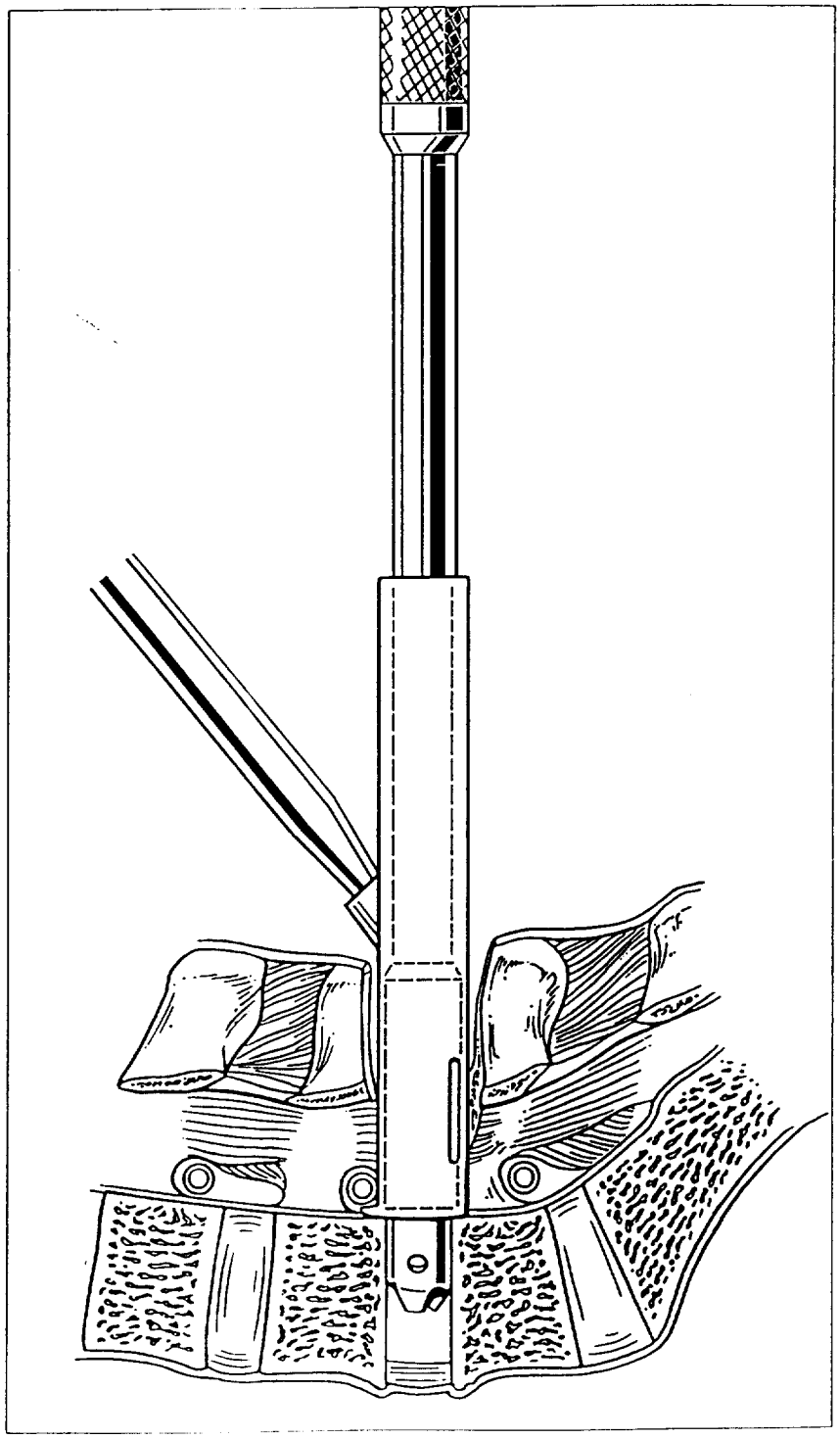


Figure 17

Place the Slap Hammer over the Drill Tube Guide and Drill Tube. Secure the anchoring teeth of the Drill Tube into the vertebral bodies by impacting the Slap Hammer until the inner surface of the Drill Tube Guide and Slap Hammer meet (Figure 18).

Once the Drill Tube is secure and alignment is verified, remove the Drill Tube Guide and Guide Pin by rotating the Drill Tube Guide clockwise and pulling straight up while applying downward pressure to the Drill Tube.

If extreme difficulty is experienced while removing the Drill Tube Guide and Guide Pin, screw the Alignment Guide Handle into the top of the Drill Tube Guide and use the Slap Hammer to vertically impact the bottom of the knob on the Alignment Guide Handle while applying downward pressure to the Drill Tube.

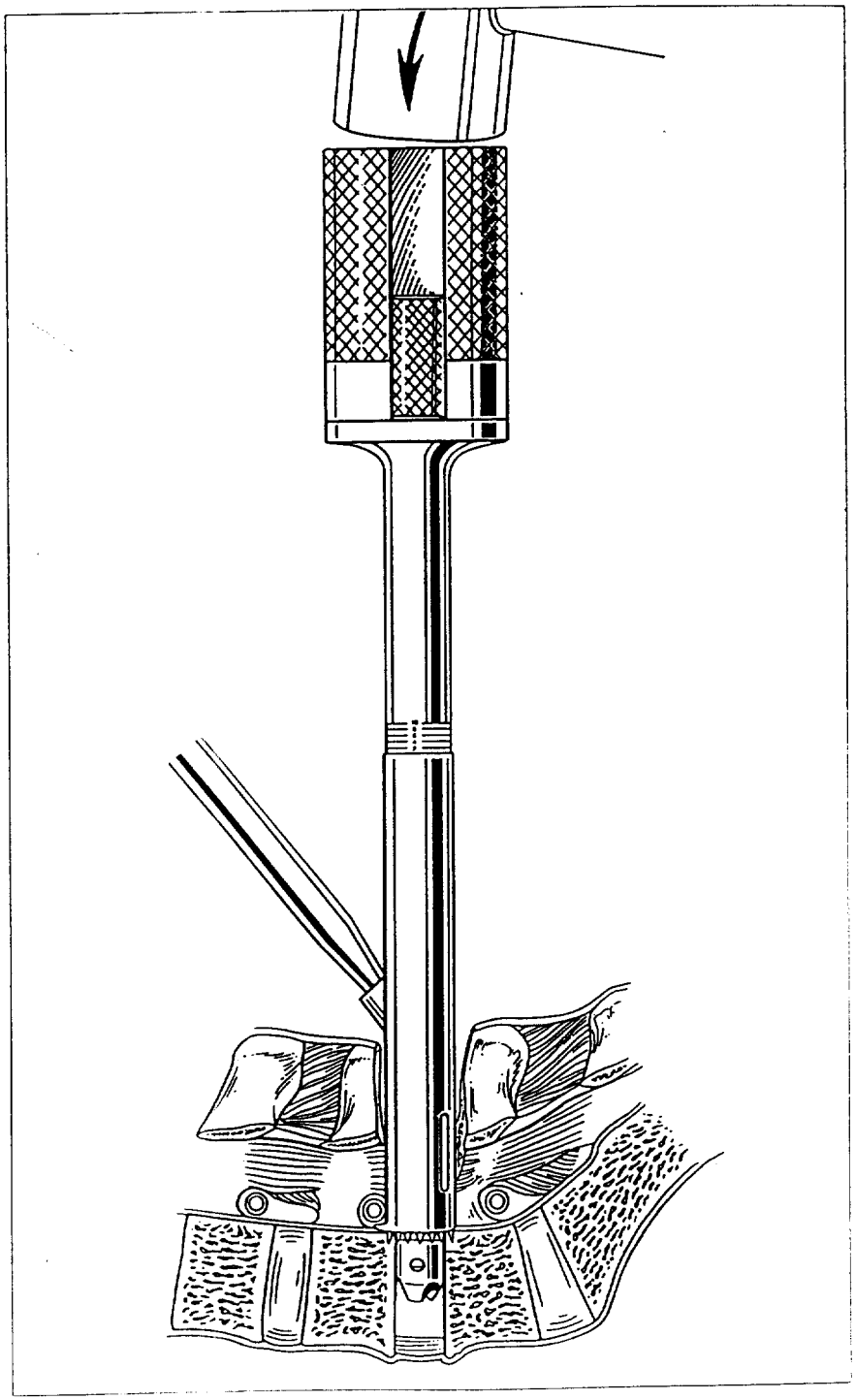


Figure 18

STEP 5 DRILL TUBE ADJUSTMENT FOR 15x20 & 17x24 IMPLANTS

Posterior Surgical Technique

NECESSARY INSTRUMENTS

Short Series Spacer

If size 15 x 20 or 17 x 24 BAK implants are to be used, it is necessary to reduce the drilling, tapping and implanting depths. This is accomplished by increasing the length of the Drill Tube.

Slide the Short Series Spacer onto the top of the Drill Tube prior to reaming. This spacer lengthens the Drill Tube and shortens the reaming, tapping and implantation depths by 4mm (Figure 19).

Implant	Reaming Depth
15 x 20	26mm
17 x 24	30mm

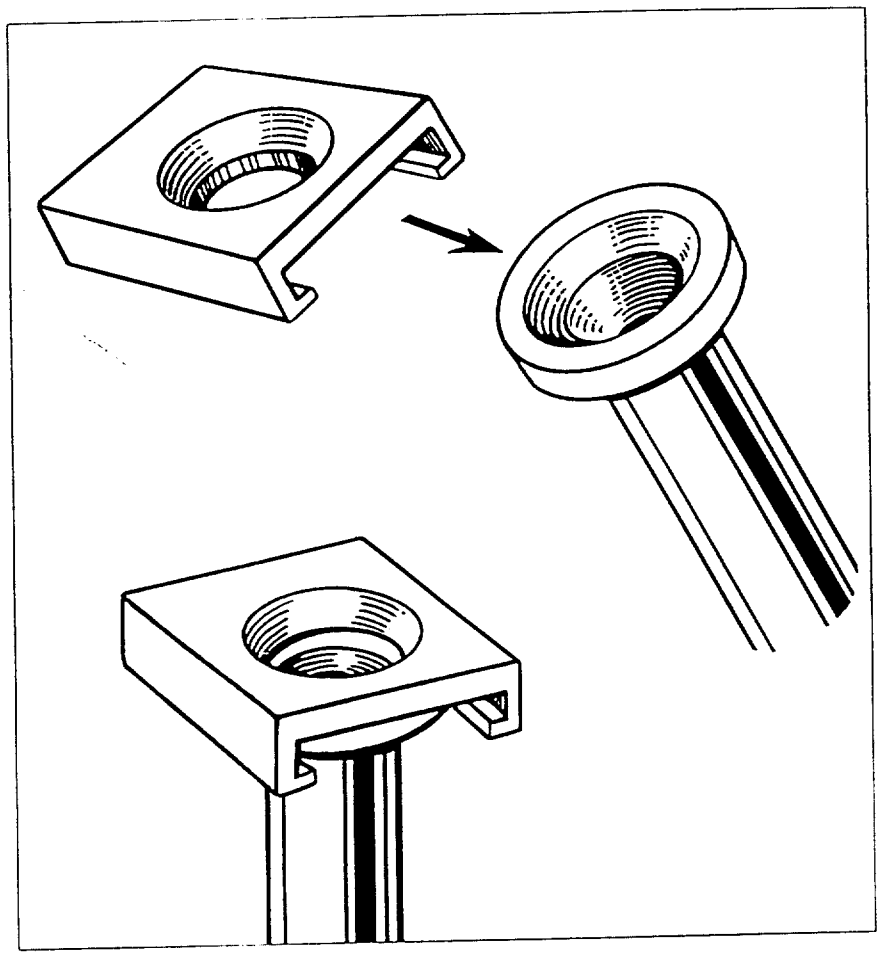


Figure 19

NECESSARY INSTRUMENTS

T-Handle
Starter Reamer
Guide Pin
Final Reamer
Pituitary Rongeur

Thread a Guide Pin the same size as the Distraction Plug onto the Starter Reamer.

While maintaining appropriate Drill Tube alignment and downward pressure, advance the Starter Reamer until the positive stop makes contact with the top of the Drill Tube. Remove the Starter Reamer while continuing to rotate it clockwise. This will prevent the Guide Pin from unthreading and ensure that debris is trapped within the reamer flutes (Figure 20).

Note: Lateral radiographic images may be taken during reaming to assess depth and endplate purchase.

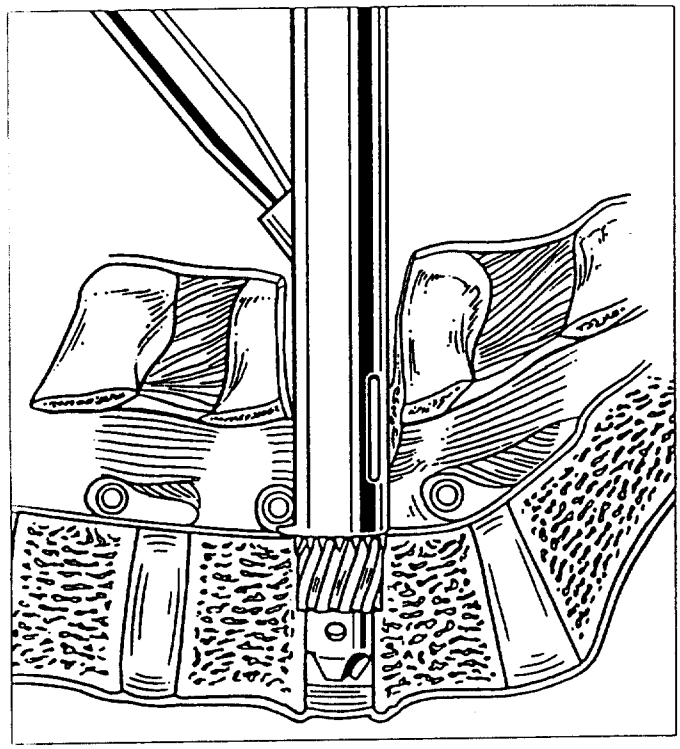


Figure 20

Insert the Final Reamer into the Drill Tube and advance until the positive stop makes contact with the top of the Drill Tube (Figure 21). Final reaming depth is noted radiographically, and saved to aid in final placement of the implant. Reaming depth should show penetration into the anterior third of the disc space. Remove the Final Reamer while rotating it clockwise.

Note: If additional reaming depth is desired, it is necessary to advance the Drill Tube further. To control the additional depth of reaming, an impaction ruling is etched onto the Drill Tube. As the Drill Tube is impacted directly, it will move relative to the Drill Tube Sheath. By noting the ruling etched onto the Drill Tube, an indication of the millimeters advanced can be assessed. If this step is deemed necessary, additional depth should be achieved in multiple small incremental advances and caution should be exercised to prevent overreaming.

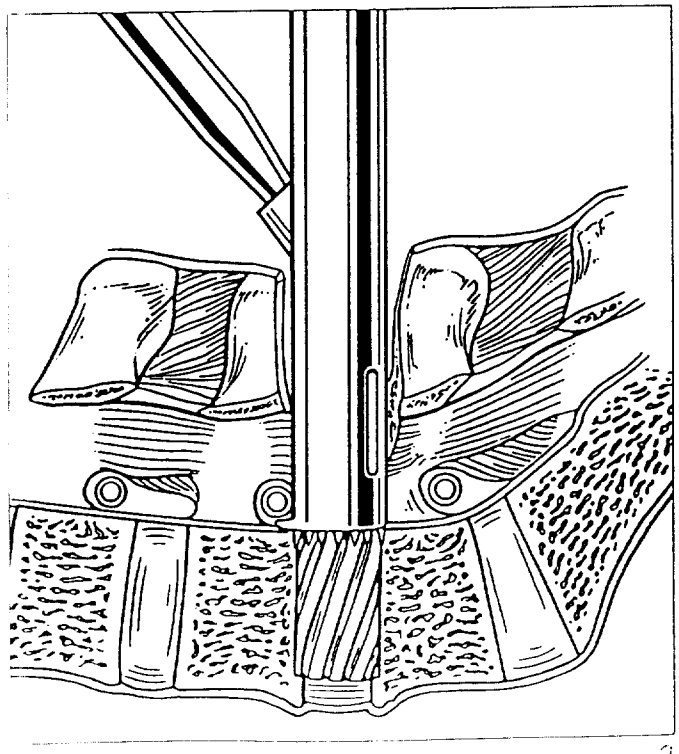


Figure 21

Once the desired final reaming depth is achieved, the Final Reamer and Drill Tube are removed and any remaining disc fragments are removed through the Drill Tube Sheath with a Pituitary Rongeur (Figure 22).

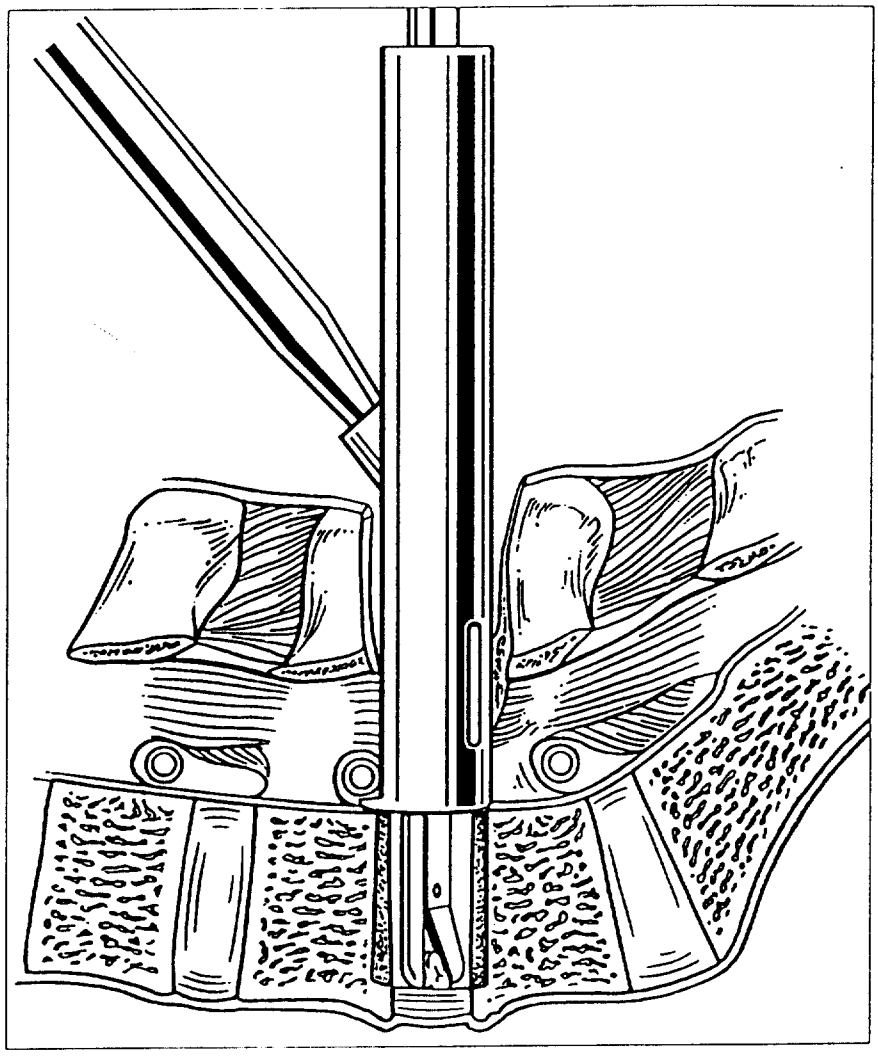


Figure 22

STEP 7 TRIAL IMPLANT PLACEMENT (OPTIONAL)

Posterior Surgical Technique

NECESSARY INSTRUMENTS

Trial Implant
Distraction Plug Inserter

Trial Implants are available to assess final drilling depth and implant location.

Thread the appropriate Trial Implant onto the Distraction Plug Inserter. Insert the Trial Implant into the prepared hole (Figure 23). A lateral radiographic image is taken to verify reaming depth and implant position. The Trial Implant should be recessed 3-4mm below the posterior margin of the vertebral bodies and show placement into the anterior third of the disc space.

Remove the Trial Implant.

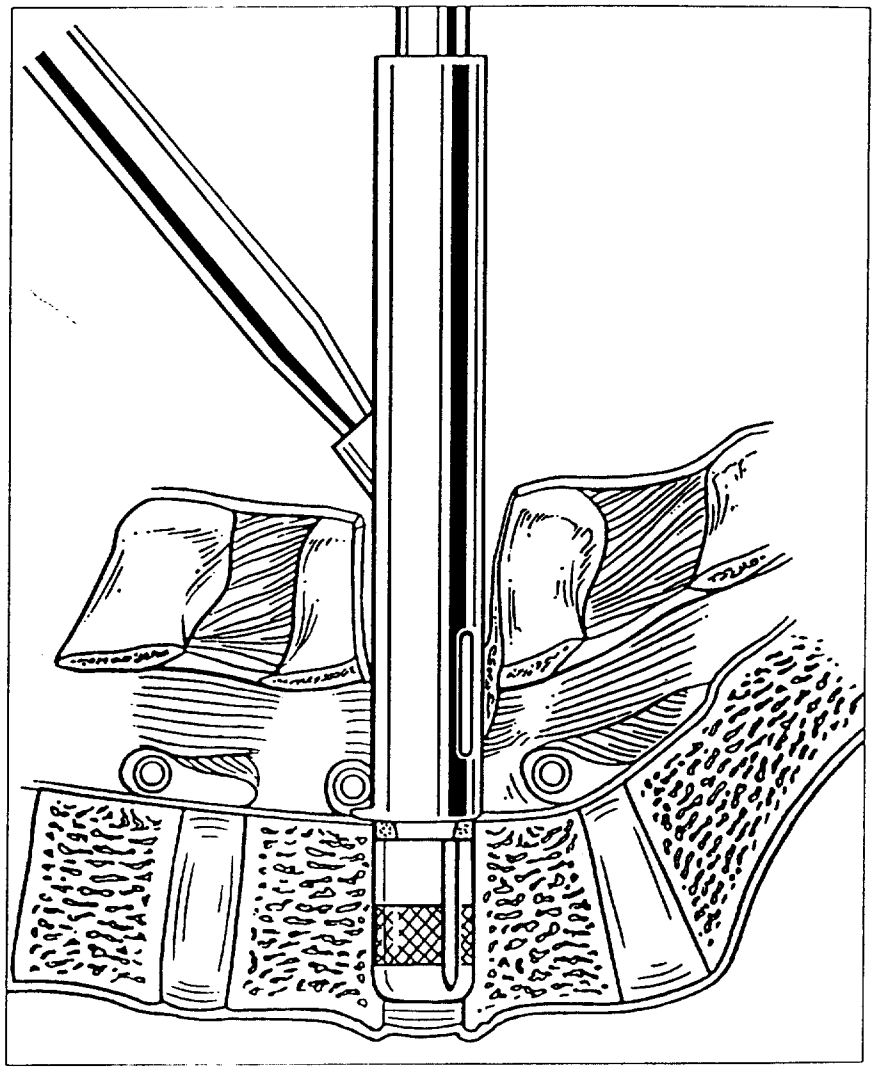


Figure 23

NECESSARY INSTRUMENTS

Bone Tap

While maintaining proper alignment, advance the Bone Tap through the Drill Tube Sheath and place the leading edge of the Tap within the hole. Apply a small amount of downward pressure to the Tap and rotate clockwise until the etch mark on the shaft of the Tap is even with the top of the Drill Tube Sheath (Figure 24).

Unthread the Tap by rotating it counter-clockwise and remove it.

Caution: Do not tap beyond the etch mark as attempting to advance beyond this point will result in stripping the bone threads.

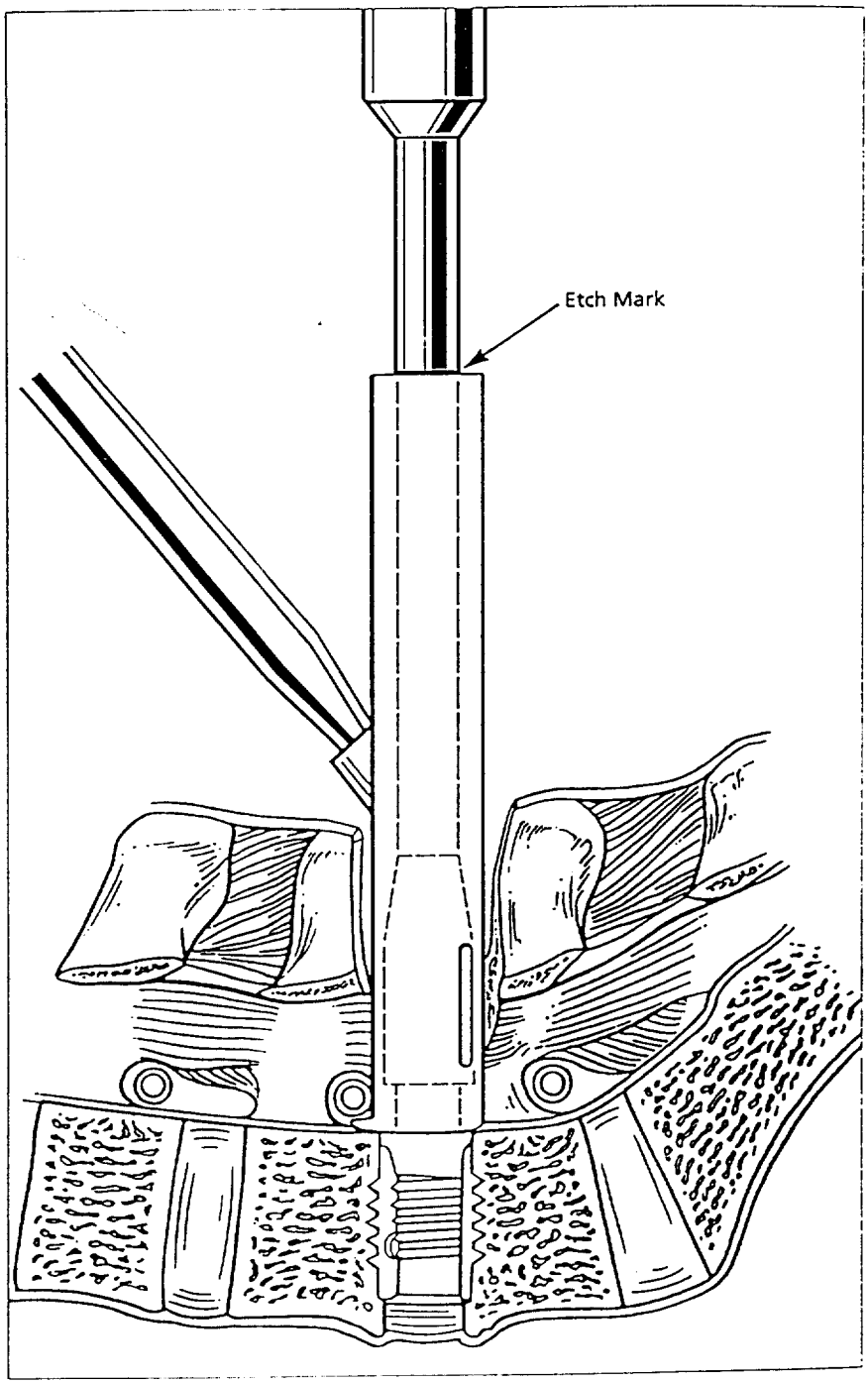


Figure 24

NECESSARY INSTRUMENTS

Implant Driver

Position the BAK implant onto the Implant Driver with the implant etching facing the handle. Secure the implant to the Implant Driver by advancing the press fit collet into the trailing chamber of the implant (Figure 25). Pack the leading chamber and large holes with morselized autograft bone. (Figure 26).

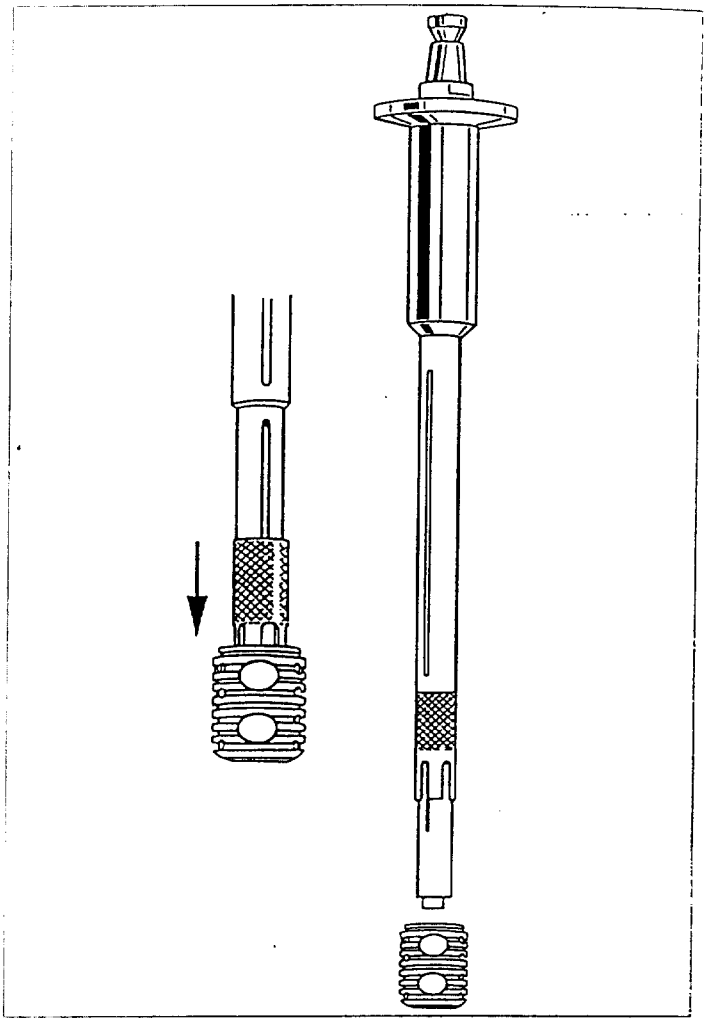


Figure 25

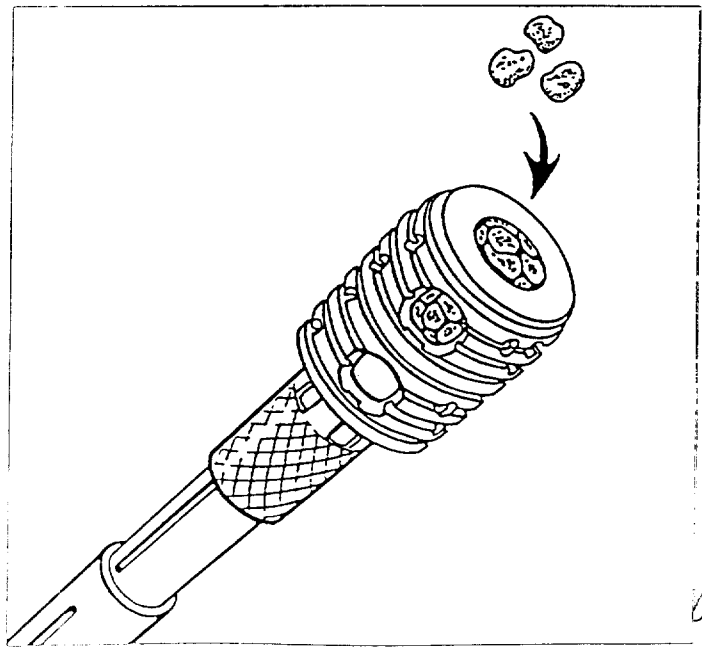


Figure 26

While maintaining the alignment angles utilized during drilling and tapping, insert the implant through the Drill Tube Sheath. Apply slight downward pressure and rotate clockwise to insert the implant. Advance the implant and Implant Driver until the etch mark on the Implant Driver shaft is even with the top of the Drill Tube Sheath (Figure 27).

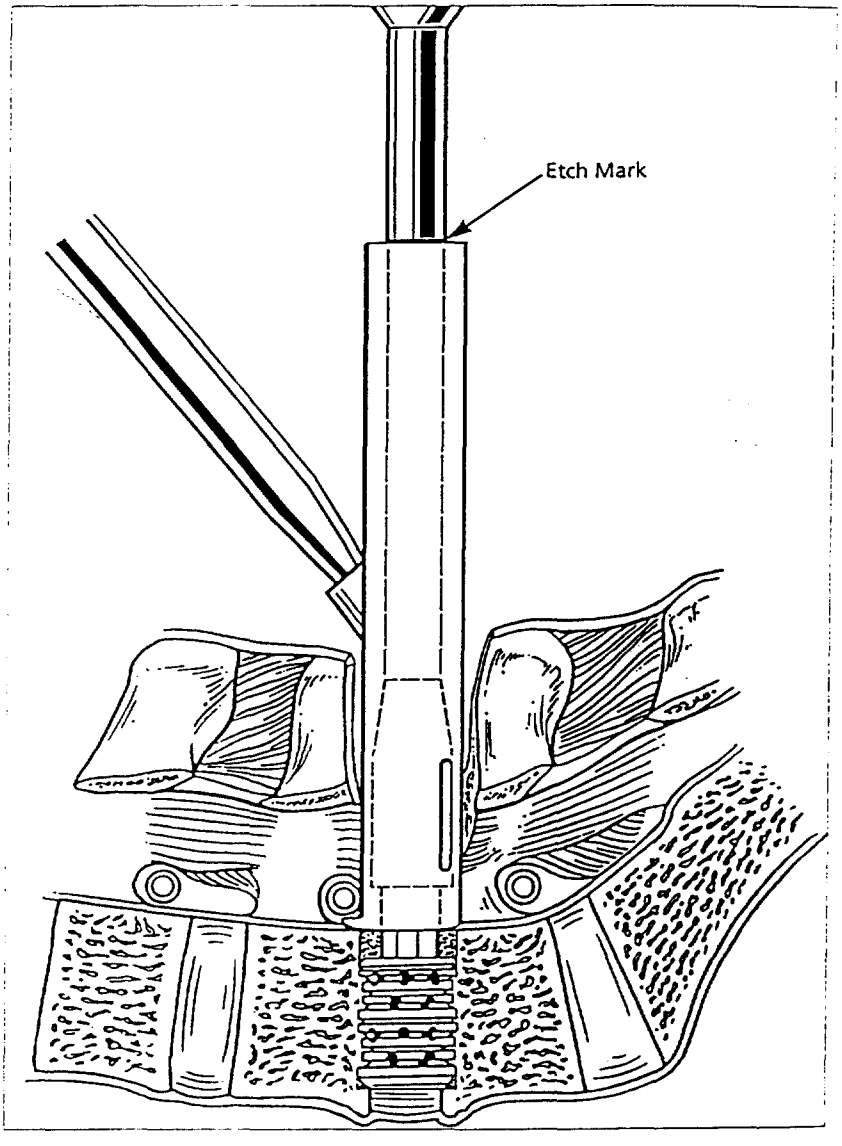


Figure 27

Proper implant orientation is achieved when the large holes are placed in a cephalad-caudal direction. This is attained when the Implant Driver T-handle is aligned parallel to the disc space.

Remove the Implant Driver by pulling straight up on the handle. This will cause the Implant Driver collet to release automatically. Remove the Drill Tube Sheath. Final implant placement is verified with a lateral radiograph. Implant placement should be recessed 3-4mm below the posterior margin of the vertebral bodies and show placement into the anterior third of the disc space.

Caution: When the etch mark is even with the top of the Drill Tube Sheath, the implant should be properly placed. If additional advancement is desired, it can be accomplished provided space is still available at the bottom of the hole. This can be assessed by comparing the reaming depth on the saved final reaming depth radiographic image to a radiographic image indicating the location of the leading edge of the implant. After removing the Drill Tube Sheath, place the Implant Driver directly into the slot in the implant. Proceed to rotate the implant clockwise, with caution, under direct vision and/or radiographic imaging. It is critical that if additional insertion is attempted, the implant must always be advancing when rotated clockwise. Once the Implant contacts the bottom of the hole, continued clockwise rotation of the Implant Driver will result in stripped bone threads.

Assess the distance between the initial implant and the Distraction Plug with the Starter Alignment Guide to ensure that medial shifting of the Drill Tube did not occur and adequate space for the second implant is still available.

Position the nerve root and dural retractors appropriately. Thread the Distraction Plug Inserter into the Dis-traction Plug. Remove the Distraction Plug by rotating clockwise while pulling straight up. If this proves difficult, the Slap Hammer will fit on the Distraction Plug Inserter and can be used to impact upward and remove the Distraction Plug.

Additional discectomy can be accom-plished at this time.

The preparation of the remaining side is identical to that described in Steps 4-9.

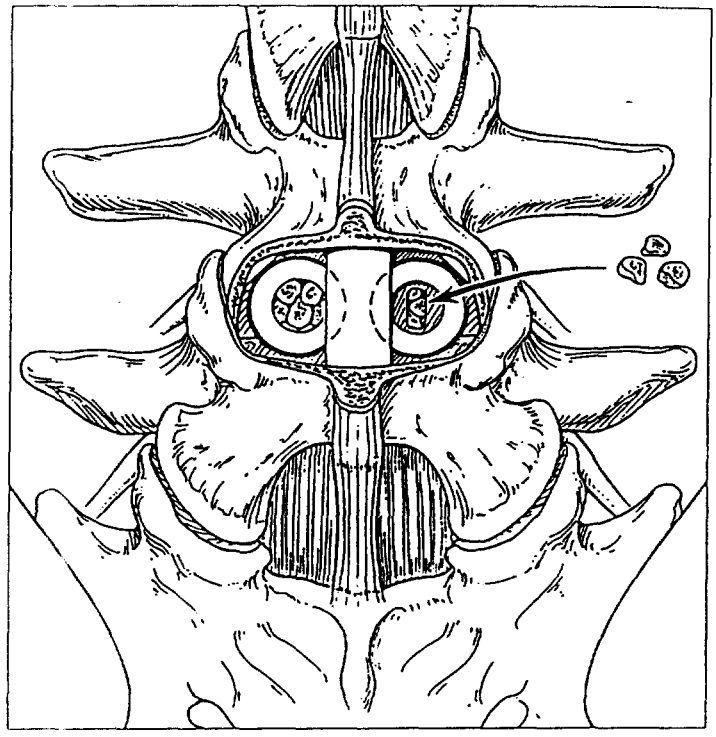


Figure 28

Note: If desired, additional bone can be packed between the implants. This is accomplished by placing bone into the second hole following tapping, packing it against the first implant, and then inserting the second implant.

Radiographic imaging will verify implant positioning within the inter-vertebral space.

Following confirmation of proper implant positioning and orientation (see note), the trailing chamber of both implants is packed with bone (Figure 28).

Note: Implants should be recessed 3-4 mm below the posterior cortical margin and have the leading edge penetrating into the anterior third of the motion segment. Additionally, implant orientation is correct when the large holes are positioned in cephalad and caudal directions. This is indicated when on visual inspection it is noted that either the Quick Disconnect T-Handle orientation is parallel to the disc space, or the long axis of the oval hole in the central web of an implant is parallel to the midline.

NECESSARY INSTRUMENTS

Endcap Inserter

Endcap placement is optional. The endcaps are designed to close off the trailing end of the implants and provide a smooth barrier to prevent the adhesion of soft tissues to the implant. In a posterior procedure, endcaps are utilized if an implant is not well recessed and a smooth barrier is desired to prevent dural adhesion to the implant. Inspection of the nerve root should be performed following endcap placement to ensure adequate freedom of the nerve root is maintained.

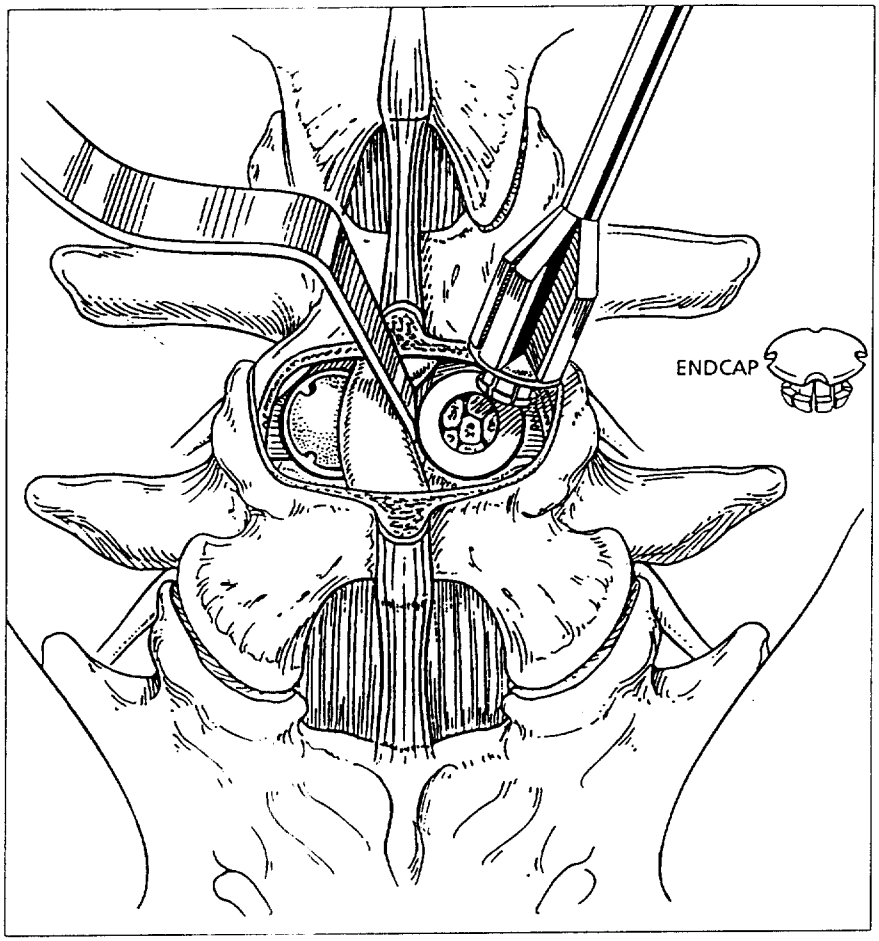


Figure 29

Attach the appropriate size endcap onto the Endcap Inserter by pressing the domed end of the endcap into the bottom of the instrument. The endcap attaches to the Endcap Inserter with a loose press fit. Following packing of the trailing chamber of the implants with bone, clear all tissue from the rim of the implant. The endcap is centered over the implant and lightly impacted into the implant (Figure 29). Proper positioning is achieved when the endcap spins freely but remains intact.

The dura is inspected for leaks and a thin layer of fat may be placed around the dura to reduce postoperative adhesions. A drain is placed if required. The retractors are removed and the wound is closed in the usual manner.

Concave Endplates:

It is not uncommon for patients with exaggerated concave endplates to present for surgery. This patient population requires a minor modification to the BAK procedure to ensure proper implant alignment, vertebral purchase and lumbar lordosis are achieved and maintained.

Prior to placement of the Distraction Plugs, it is necessary to remove the large marginal osteophytes at the location of the 8mm drilling sites. This can be easily accomplished with a 1/4 inch osteotome or Kerrison rongeur.

This step is necessary to achieve an accurate representation of the disc height which needs to be bridged by the implant and to prevent the motion segment from being "tipped" into local kyphosis.

Spondylolisthesis:

It is not uncommon for patients with low Grade I spondylolisthesis or retrolisthesis to present for surgery. This population requires a minor modification to the BAK procedure to ensure proper implant alignment and vertebral purchase are achieved.

If the slip is mobile, correction of the spondylolisthesis can many times be affected by distracting the motion segment incrementally on one side and then the other until the proper Distraction Plug is identified. If this is possible and complete reduction is achieved, proceed with the implantation in the usual fashion.

If the spondylolisthesis does not fully reduce, the Drill Tube and Drill Tube Sheath may not sit evenly over the posterior margin of the disc space. Rather, they will angle such that drilling would cut much more out of one vertebra than the other.

To correct this situation, following impaction of the Drill Tube, use lateral radiographs to modify the angle of the Drill Tube to be parallel with the endplates of the disc. After realignment, gently strike the top of the tube to firmly reseat the teeth.

Implant Contact:

If alignment has been compromised, the threads on the implants may mesh together during insertion. If this occurs, there is a possibility that as the second implant is screwed in, it will unscrew the first implant.

If this occurs, position the first implant appropriately and hold it stationary by inserting a small osteotome in the central slot. This will prevent the first implant from unscrewing as the second implant is screwed in.

Bone Thread Stripping:

The BAK implants require thread purchase within the vertebral bodies to achieve optimal stability. As previously stated, great care should be taken not to damage the bone threads during implantation.

If damage should occur and the implant is deemed unstable, corrective action to regain a stable condition should be taken. The BAK implant sizing has been established with incremental increases of 2.0mm from one size to the next.

If the bone threads become stripped, the action which caused the stripping will create a hole equivalent in size to the minor diameter of the next larger diameter implant.

In this instance, the reaming depth is inspected with a Trial Implant to ensure the larger implant can be positioned behind the posterior cortical margin. If it does not fit, careful retraction of the dura and nerve root is accomplished. The Final Reamer is then directly introduced and carefully advanced under radiographic control until the Trial Implant fits.

Following Trial Implant inspection and subsequent additional reaming where necessary, the larger Tap is advanced directly into the hole to cut the first few threads. The larger implant is then assembled onto the Implant Driver, packed with bone, and threaded into the hole.

In situations where the 17mm implants were used and stripping occurred, a bone dowel of 20mm in diameter is necessary to fill the hole as the 17mm diameter is the largest BAK implant available.

The following table illustrates the implants necessary to re-establish stability following bone thread stripping:

Implant Stripped	Recovery Device
13 x 20 mm	15 x 20mm
15 x 20 mm	17 x 24mm
15 x 24mm	17 x 24mm
17 x 24mm	20mm bone dowel
17 x 28mm	20mm bone dowel

APPENDIX II POSTOPERATIVE CARE

Posterior Surgical Technique

Immediate postoperative care includes:

- Routine monitoring of vital signs and neurological status.
- Administration of appropriate pain medication.
- If nasogastric tubes and/or Foley catheters are utilized, discontinue within 24 hours post-op.
- The patient is encouraged to ambulate as tolerated the day of surgery. The use of a brace is at the discretion of the surgeon.
- Diet is advanced as tolerated.
- Patients should be instructed to restrict activity until advised by their surgeon.

APPENDIX III BAK IMPLANTS

Posterior Surgical Technique

The BAK implants are constructed of 6Al-4V titanium alloy and available in the following dimensions.

Part Number	Size	Minor Dia. (mm)	Major Dia. (mm)	Length (mm)	Drilling Depth (mm)	Implant Volume (cc)*
3000-1320-00	13 x 20	13	15.5	20	26	2.5
3000-1520-00	15 x 20	15	17.5	20	26	3
3000-1524-00	15 x 24	15	17.5	24	30	3.5
3000-1724-00	17 x 24	17	19.5	24	30	4
3000-1728-00	17 x 28	17	19.5	28	34	5

Endcaps are optional with the BAK system. They are designed to enclose the graft within the device. Endcaps are constructed from ultra high molecular weight polyethylene. Sizes correspond to the implants:

Sizes

13mm

15mm

17mm

* *Refers to air volume of an individual implant. More bone graft will be required to tightly pack implants and spaces around the implants.*

The BAK system utilizes slight variations in drill tube combinations when implants are inserted from an anterior vs. posterior approach.

These variations are necessary to minimize the retraction of neural structures during posterior implantation of the BAK.

Posterior

Implant size	Drill Tube	Drill Tube Guide	Sheath
13mm	4010-1425	4010-1424	4010-1350
15mm	4010-1625	4010-1624	4010-1550
17mm	4010-1825	4010-1824	4010-1750

Anterior

Implant size	Drill Tube	Drill Tube Guide	Sheath	Drill Tube Sleeve
13mm	4010-1625	4010-1624	4010-1351	4010-1326
15mm	4010-1825	4010-1824	4010-1551	4010-1526
17mm	4010-2025	4010-2024	4010-1751	4010-1726

SPINETECH®

7375 Bush Lake Road
Minneapolis, MN 55439-2029
U.S.A
Telephone: 612.832.5600 or 1.800.655.2614
Fax: 612.832.5620 or 1.800.430.9110